

# BACK IN THE GAME

## BRAND BOOK 2024



## INTRODUCTION



*Dear Colleagues,*

*The TTh market is rapidly evolving and growing due to a surge in the aging male population<sup>1</sup> and medicine's increasing acceptance of men's health and well-being as a distinct specialty.<sup>2</sup>*

*With the publication of the TRAVERSE study, now is the time to leverage these opportunities with confidence. ANDROGEL®'s unmatched CV and prostate safety profile, robust efficacy on low libido, and the option of injectable TESTOSTERONE BESINS to improve longer-term adherence, will ensure we maintain and extend our position as market leader.*

*The "Back in the Game" creative route delivers an energetic, positive and confident approach to TTh. Showcasing our TRAVERSE data will help ensure HCPs understand that ANDROGEL® and TESTOSTERONE BESINS provide the trusted choice for individualized therapy. Let's make BESINS the one-stop shop for male health.*

*We would like to thank our affiliate colleagues for their invaluable input into this campaign, which will raise our brands to the next level and beyond by providing you with the essential tools you need to maximize traction in your market.*

*Kind regards,*

*The Global Medical and Marketing Team*

**HCP:** Healthcare Professional; **CV:** Cardiovascular; **TTh:** Testosterone Therapy.

1. Kanakis GA, et al. Maturitas. 2023 178:107854.

2. Davis S. Trends in Men's Health: More than Testosterone. Available at: <https://www.healthcareers.com/career-resources/trends-and-data/trends-in-mens-health-careers>. Accessed March 2024.

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# I. MEN'S HEALTH MARKET LANDSCAPE

## A NEW ERA IN MEN'S HEALTH

### What's happening in the TTh market right now?

The aging male population is increasing, so demand for TTh is also increasing<sup>1,2</sup>

The TTh market was valued at \$1.9bn in 2022 and will reach \$2.9bn by 2032<sup>1</sup>

An increasing awareness among HCPs regarding men's health and overall well-being<sup>1,2</sup>

Academic medical centers have begun to establish clinics to provide an holistic approach to men's health<sup>2</sup>

Online male health clinics offer treatments for "Low T" with regular testosterone injections and lab monitoring<sup>2</sup>

**HCP:** Healthcare Professional; **TTh:** Testosterone Therapy.

1. Allied Market Research. Testosterone Replacement Therapy Market by Product Type, Active Ingredient and End User: Global Opportunity Analysis and Industry Forecast 2024. Available at: <https://www.prnewswire.co.uk/news-releases/testosterone-replacement-therapy-market-to-reach-2-9-billion-globally-by-2032-at-4-5-cagr-allied-market-research-302095725.html>. Accessed June 2024.

2. Davis S. Trends in Men's Health: More than Testosterone. Available at: <https://www.healthcareers.com/career-resources/trends-and-data/trends-in-mens-health-careers>. Accessed June 2024.

# PATIENT INSIGHTS<sup>1</sup>



“Men are embarrassed to see doctors about TD symptoms”

“Men want their TD symptoms treated”

“Similar satisfaction rates between TTh gels, injections & pellets”

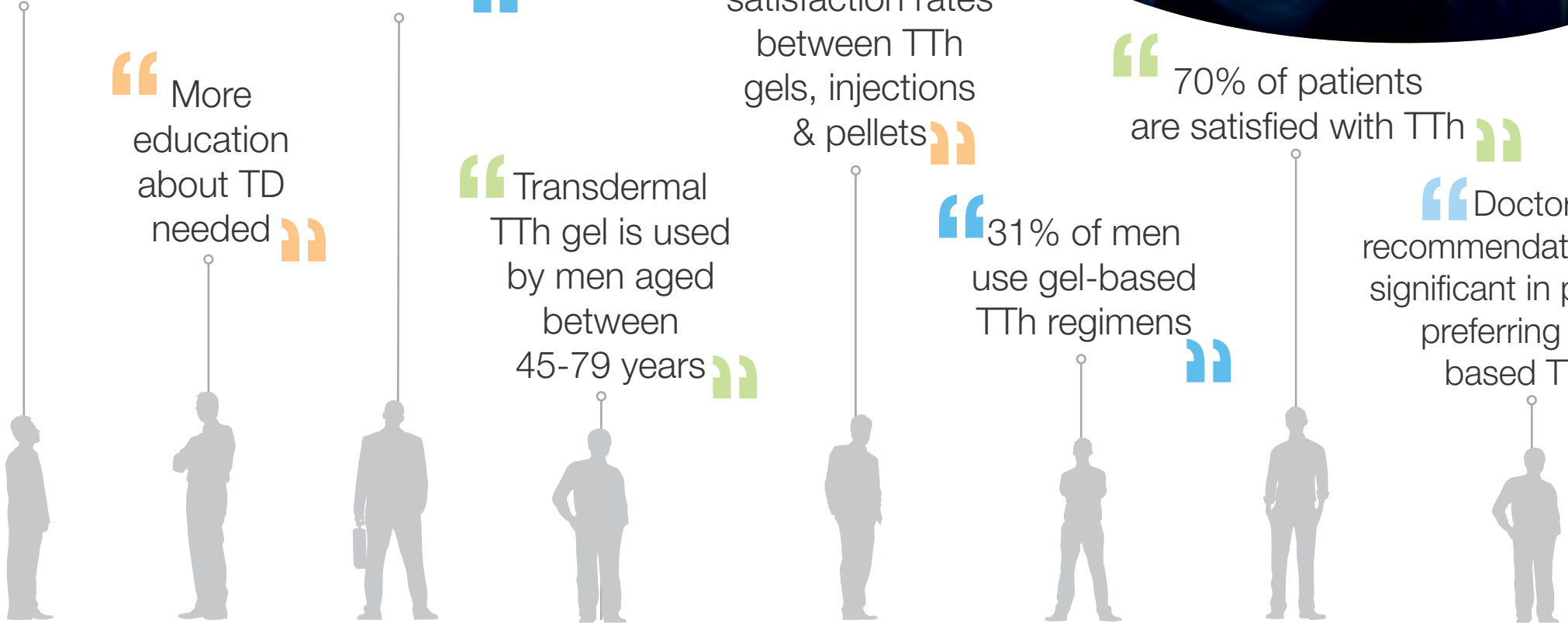
“70% of patients are satisfied with TTh”

“More education about TD needed”

“Transdermal TTh gel is used by men aged between 45-79 years”

“31% of men use gel-based TTh regimens”

“Doctor recommendations are significant in patients preferring gel-based TTh”



TD: Testosterone Deficiency; TTh: Testosterone Therapy.

1. Kovac JR, et al. J Sex Med. 2014;11(2):553-562.

# MEDICAL INSIGHTS

## Low libido is an early sign of testosterone deficiency<sup>1</sup>

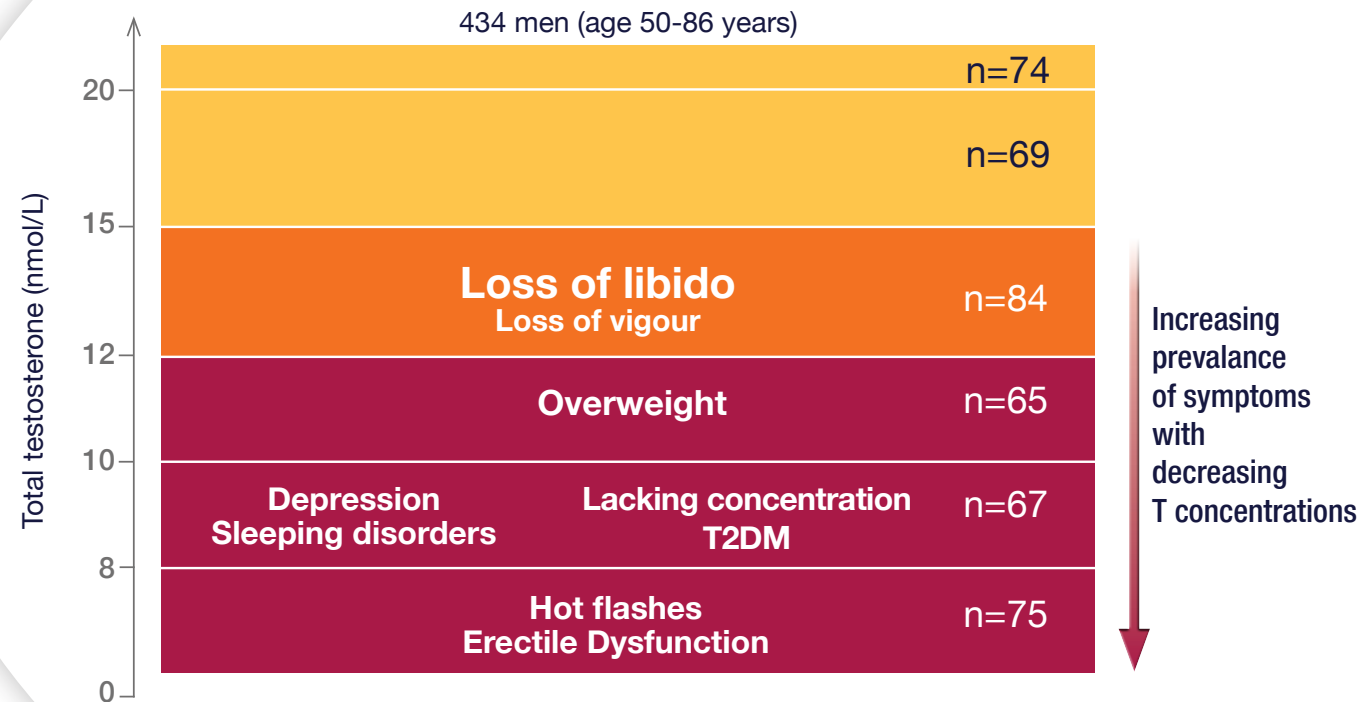
Prevalence of TD in men aged 30–79 years is between 2.1% to 12.3%<sup>2</sup>

Prevalence increases with age and can profoundly disrupt the lives of men<sup>3</sup>

TD prevalence in obese men is 52% (BMI >30 kg/m<sup>2</sup>) and 50% in men with Type 2 DM<sup>4</sup>

Fewer than 10% of men with TD receive TTh<sup>5</sup>

Few older men are tested for TD even when they present with hypogonadal symptoms<sup>6</sup>



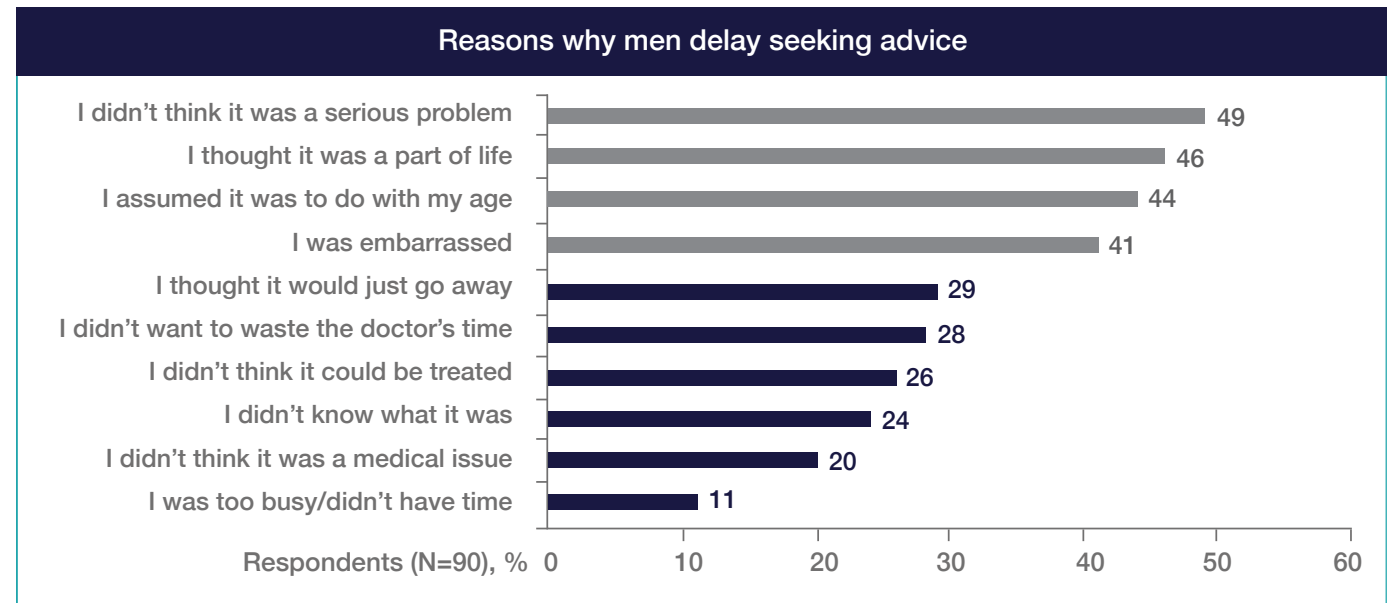
**BMI:** Body Mass Index; **DM:** Diabetes Mellitus; **TD:** Testosterone Deficiency; **TTh:** Testosterone Therapy.

1. Zitzmann M, et al. *Journal of Clinical Endocrinology & Metabolism*. 2006; 91(11):4335-4343.
2. European Male Aging Study (EMAS). *New England Journal of Medicine*. 2010;363(2):123-135.
3. Araujo AB, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2007;92(11):4241-4247.
4. Khera M, et al. *The Journal of Sexual Medicine*. 2016;13:1787e1804.
5. Tostain JL, et al. *Nature Clinical Practice Urology*. 2008;5:388-396.
6. Livingston M, et al. *International Journal of Clinical Practice*. 2020;74:e13607.



# REASONS WHY MEN DON'T SEEK TREATMENT

Lack of awareness and shame contribute to the under-diagnosis of TD<sup>1,2</sup>



TD: Testosterone Deficiency.

1. Edwards D. Meeting Report. British Society for Sexual Medicine. October 2016.

2. Mayor S. Article in *Prescriber*: 42-46. October 2016.



# CLINICAL UPDATE

## Evidence-based actions on hypogonadism<sup>1</sup>



### Standardising the biochemical confirmation of adult male hypogonadism: A joint position statement by the Society for Endocrinology and Association of Clinical Biochemistry and Laboratory Medicine

#### THE CURRENT PROBLEM<sup>1</sup>

- Inter-assay variation between immunoassays and mass spectrometry methods hampers biochemical confirmation of male hypogonadism
- Some laboratories use assay manufacturer reference ranges that do not mirror assay performance characteristics\*

\*Lower limit of T normality ranges from 4.9 nmol/L to 11 nmol/L

**Commercially produced reference ranges have no discernible clinical value for the management of male hypogonadism.**

## Evidence-based actions on hypogonadism<sup>1</sup>



### CONFIRMATION STATEMENT FOR AIDING INTERPRETATION OF SERUM T REPORTS

- Patients with suggestive clinical features and 2 consecutive morning, fasted levels of  $<8$  nmol/L ( $<230$ ng/dL) are likely to have hypogonadism
- Morning fasted levels of 8–12 nmol/L (230–346ng/dL) may be seen in eugonadal or hypogonadal men, so require careful clinical correlation
  - Levels of  $>12$  nmol/L are not usually consistent with hypogonadism
- One reading of  $>12$  nmol/L ( $>346$ ng/dL) usually excludes hypogonadism, even if other readings are lower
- Measurements in a non-fasted state, during acute illness, or later than 11 a.m. cannot be used to diagnose hypogonadism.





# CLINICAL UPDATE

## TRAVERSE study snapshot


### ANDROGEL: UNMATCHED SAFETY IN TTh

TRAVERSE: A phase 4, multicenter, noninferiority, event-driven safety trial that randomized more than 5,200 men aged 45 to 80 years in a double-blind manner to daily transdermal 1.62% testosterone gel or matching placebo gel.

### ROBUST CV & PROSTATE SAFETY PROFILE

-  Androgel<sup>®</sup> was non-inferior to placebo for occurrence of MACE during a mean of 33 months of follow-up with a low overall incidence of AEs.<sup>1</sup>
-  No significant difference in the incidence of high-grade or any prostate cancer and other adverse prostate events between cohorts treated with Androgel<sup>®</sup> and placebo.<sup>2</sup>

### SIGNIFICANTLY IMPROVED LIBIDO:

-  Androgel<sup>®</sup> significantly improved sexual activity, hypogonadal symptoms and sexual desire vs placebo, maintaining these effects for 2 years.<sup>3</sup>

**AE:** Adverse Events; **MACE:** Major Adverse Cardiovascular Event; **TTh:** Testosterone Therapy.

1. Lincoff AM, et al. *N Engl J Med.*2023; DOI: 10.1056/NEJMoa2215025.

2. Bhasin S, et al. *JAMA Netw Open.*2023;6(12):e2348692.

3. Pencina KM, et al. *J Clin Endocrinol Metab.*2023;DOI:1010/clinem/dgad484.



## II. GLOBAL BRAND STRATEGY

**Core values:**  
DYNAMIC  
CONFIDENT  
VIGOROUS

## INSIGHT

Endocrinologists and urologists need reassurance that TTh will improve TD symptoms, such as low libido, without impacting long-term CV and prostate safety.

**Choose gold-standard Androgel®** – the first and only TTh with long-term CV and prostate safety data from TRAVERSE – the largest study ever performed using TTh.<sup>1,2</sup>

**THAT** significantly improves low libido and sexual function over 2 years when prescribed first-line.<sup>3</sup>

**FOR** men who want to improve their low libido, vigor, and zest for life.

**CV:** Cardiovascular; **TTh:** Testosterone Therapy.

1. Lincoff AM, *et al.* N Engl J Med.2023; DOI: 10.1056/NEJMoa2215025.

2. Bhasin S, *et al.* JAMA Netw Open.2023;6(12):e2348692.

3. Pencina KM, *et al.* J Clin Endocrinol Metab.2023;DOI:1010/clinem/dgad484.

**Core values:**  
DYNAMIC  
CONFIDENT  
VIGOROUS

## BECAUSE

- It demonstrates proven CV safety\* (n=2,601; P<0.001) vs PBO (n=2,603) over an average treatment duration of 22 months and follow-up of 33 months<sup>1</sup>
- It demonstrates proven prostate cancer safety\* over a mean of 33 months of follow-up (n=2,601; P=0.51) vs PBO (n=2,603)<sup>2</sup>
- It provides significant efficacy\* from baseline over 24 months on sexual activity (n=587; P=0.011) and sexual function\* (n=587; P=0.019) vs PBO (n=574)<sup>3</sup>
- It provides significant correction of anemia\* for up to 48 months (n=390; P=0.002) vs PBO (n=425)<sup>4</sup>
- It provides significant mood improvements\* in men with depressive symptoms (n=26; P=0.008) vs PBO (n=23) and among all men (N=1,308; P=0.001) vs PBO (n=1,135)

- for up to 24 months as measured by HIS-Q mood domain score<sup>5</sup>
- In men with significant depressive symptoms (n=2643), TTh was associated with significantly greater improvements in mood (p=0.008)<sup>5</sup>
- It significantly increases lean body mass<sup>†</sup> (n=123; P=0.0001) from baseline and throughout treatment<sup>7</sup>
- It provides a gradual and progressive increase in BMD<sup>†</sup> of the hip (n=123; P=0.0004) and spine (n=123; P=0.0001)<sup>7</sup>
- It can be easily titrated to each patient's needs<sup>8</sup>
- Is the global leader in transdermal testosterone<sup>9</sup>

**Brand  
mission**

## SO THAT

HCPs can restore libido in men by treating TD with confidence in long-term CV and prostate safety.

\*Androgel® 1.62%; †Testosterone gel 1.0%

**AE:** Adverse Events; **BDM:** Bone Mineral Density; **CV:** Cardiovascular; **HCP:** Healthcare Professional; **HIS-Q:** Hypogonadism Impact of Symptoms Questionnaire; **PDQ-Q4:** Psychosexual Daily Questionnaire Question 4; **PBO:** Placebo; **TD:** Testosterone Deficiency; **TTh:** Testosterone Therapy.

1. Lincoff AM, et al. *N Engl J Med.* 2023; DOI: 10.1056/NEJMoa2215025.

2. Bhasin S, et al. *JAMA Netw Open.* 2023;6(12):e2348692.

3. Pencina KM, et al. *J Clin Endocrinol Metab.* 2023; DOI:10.1010/clinem/dgad484.

4. Pencina KM, et al. *JAMA.* 2023;6(10):e2340030. DOI:10.10012024.

5. Bhasin S, et al. *J Clin Endocrinol Metab.* 2024; 109(7):1814-1826.

6. Snyder PJ, et al. *New England Journal of Medicine.* 2016;374(7):611-624.

7. Wang C, et al. *The Journal of Clinical Endocrinology & Metabolism.* 2004;89(5):2085-2098.

8. Androgel® Summary of Product Characteristics.

9. IQVIA. Data on File. 2024.

**Core values:**  
PATIENT-PREFERRED  
COST-EFFECTIVE  
CONVENIENT

## INSIGHT

Testosterone Besins is the new, cost-effective, and long-acting injectable testosterone from BESINS for men who are ready to transition away from a daily transdermal gel.

**THAT** facilitates the treatment of key symptoms of TD in the longer term.

**FOR** men who want to restore their libido, energy, and zest for life with a patient-preferred medication.

## BECAUSE

- It is more cost-effective than Nebido® regarding pricing and reimbursement<sup>1</sup>
- It delivers stable testosterone levels for an injection interval of up to 3 months<sup>2</sup>;
- It improves patient adherence thanks to a limited number of injections per year<sup>2</sup>
- It demonstrates significant improvements in libido, fatigue, low mood, and low vigor<sup>2</sup>

- It reduces help reduce progression from pre-diabetes to T2DM when administered alongside lifestyle improvements<sup>3</sup>
- It is the patient-preferred delivery route<sup>4</sup>
- It is the long-term treatment of choice after initiation with AndroGel® or other short-acting testosterone.<sup>4</sup>
- BESINS HEALTHCARE has a trusted heritage in TD treatment.

## SO THAT

HCPs prescribe the patient-preferred delivery route that improves long-term adherence.

**Brand  
mission**

**HCP:** Healthcare Professional; **TD:** Testosterone Deficiency; **T2DM:** Type 2 Diabetes Mellitus.

# ANDROGEL® & TESTOSTERONE BESINS

## KEY MESSAGES

### Burden of TD

- TD profoundly disrupts the lives of men on a physical/mental level, negatively impacting their quality of life<sup>1</sup>
- Low libido is an early sign and symptom of TD<sup>2</sup>
- Overall prevalence of TD in men aged 30–79 years is estimated to be between 2.1–12.3%, depending on the diagnostic criteria used and the patient populations studied<sup>3</sup>
- Prevalence in obese men is 52% (BMI > 30 kg/m<sup>2</sup>) and 50% in men with T2DM<sup>4</sup>
- Certain comorbidities increase the risk of TD: long-term opioid users, dyslipidaemia, cancer, and polypharmacy (≥6 medications), yet <10% receive TTh<sup>5–7</sup>
- Testing reference values for low testosterone differ between laboratories and assay type, which can lead to under-diagnosis. Many older men also go untested for low T despite related comorbidities<sup>7</sup>
- Commercially produced reference ranges have no discernible clinical value for the management of male hypogonadism. Therefore evidence-based action levels should be used for diagnosis
- Prompt testing and treating can help prevent the accumulation of worsening TD symptoms caused by decreasing testosterone levels over time<sup>2</sup>

### Unsurpassed efficacy on libido

- Provides significant efficacy from baseline over 24 months on sexual activity (n=587; P=0.011) and sexual function (n=587; P=0.019) vs PBO (n=574)<sup>8</sup>
- Provides significant increases in sexual activity from 3 months (N=790; P<0.001) as measured by PDQ-Q4 score<sup>9</sup>

**BMD:** Bone Mineral Density; **HIS-Q:** Hypogonadism Impact of Symptoms Questionnaire; **PDQ-Q4:** Psychosexual Daily Questionnaire Question 4; **PBO:** Placebo; **TD:** Testosterone Deficiency; **TTh:** Testosterone Therapy; **T2DM:** Type 2 Diabetes Mellitus.

1. Traish AM, et al. *The American Journal of Medicine*. 2011;124(7):578–587. 2. Zitzmann M, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2006;91(11):4335–4343. 3. European Male Aging Study (EMAS). *New England Journal of Medicine*. 2010;363(2):123–135. 4. Khera M, et al. *The Journal of Sexual Medicine*. 2016;13:1787e1804. 5. Burte C, et al. *Progrès en urologie*. 2021;31:458–476. 6. Tostain JL, et al. *Nature Clinical Practice Urology*. 2008;5:388–396. 7. Livingston M, et al. *International Journal of Clinical Practice*. 2020;74:e13607. 8. Pencina KM, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2023;109(2):569–580. 9. Snyder PJ, et al. *New England Journal of Medicine*. 2016;374(7):611–624.



# ANDROGEL® & TESTOSTERONE BESINS KEY MESSAGES

## Broad efficacy on TD signs and symptoms

- Provides significant correction of anaemia\* for up to 48 months (n=390; P=0.002) vs PBO (n=425)<sup>10</sup>
- In men with significant depressive symptoms (n=2643) TTh was associated with significantly greater improvements in mood (p=0.008)<sup>11</sup>
- TTh was also associated with greater improvements in the energy domain score more than placebo (p=0.01)<sup>1</sup>
- Significantly increases lean body mass† (n=123; P=0.0001) from Baseline and throughout treatment<sup>12</sup>
- Provides a gradual and progressive increase in BMD† of the hip (n=123; P=0.0004) and spine (n=123; P=0.0001)<sup>12</sup>

## Unmatched safety profile

- Androgel® is the first and only TTh brand with long-term significant CV and prostate safety data (TRAVERSE):
  - Proven CV safety\* (n=2,601; P<0.001) vs PBO (n=2,603) over an average treatment duration of 22 months and follow-up of 33 months<sup>13</sup>
  - Proven prostate cancer safety\* over a mean of 33 months of follow-up (n=2,601; P=0.51) vs PBO (n=2,603)<sup>14</sup>

## Tailored and trusted

- Tailor 1<sup>st</sup>-line treatment with easily titratable Androgel®<sup>15</sup>
- Maintain libido levels and improve long-term adherence with injectable Testosterone Besins<sup>16</sup>
- BESINS is the global leader in transdermal testosterone<sup>17</sup>

\*Androgel® 1.62%; †Testosterone gel 1.0%

**BMD:** Bone Mineral Density; **HIS-Q:** Hypogonadism Impact of Symptoms Questionnaire; **PDO-Q4:** Psychosexual Daily Questionnaire Question 4; **PBO:** Placebo; **TD:** Testosterone Deficiency; **TTh:** Testosterone Therapy; **T2DM:** Type 2 Diabetes Mellitus.

**10.** Pencina KM, et al. *JAMA*. 2023;6(10):e2340030. DOI:10.10012024. **11.** Bhasin 2024 (Abstract only from *The Journal of Clinical Endocrinology & Metabolism*)

**12.** Wang C, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2004;89(5):2085-2098. **13.** Lincoff AM et al. *New England Journal of Medicine*. 2023; DOI: 10.1056/NEJMoa2215025.

**14.** Bhasin S et al. *JAMA Network Open*. 2023;6(12):e2348692. **15.** Androgel® SMPC. **16.** Testosterone Besins- SMPC. **17.** IQVIA. Data on File. BESINS 2024.



## III. GLOBAL CAMPAIGN

## Communication objective

Reassure HCPs that Androgel® and Testosterone Besins can safely and effectively treat TD to help hypogonadal men resolve their symptoms and get “BACK IN THE GAME”.

## Brand tagline

“BACK IN THE GAME”

## Understanding the message behind the concept

Men want to treat their low libido and increase their vigor and zest for life, so they can reclaim their masculinity with the only TTh with an unmatched CV and prostate safety profile that significantly improves low libido and sexual function to help men get back in the game.

## Leveraging the emotion behind the concept

Our “BACK IN THE GAME” man wants to treat his low libido, because he’s a modern man in touch with his feelings and desires. He’s also clear that he wants a safe and effective TTh that works in tandem with his busy life

Tested  
with 116HCPs in  
4 key countries

Testosterone Deficiency • low libido • low vigor • low mood

# BACK IN THE GAME

**Androgel**  
16.2 mg/g gel (testosterone)

**TESTOSTERONE BESINS**  
1000 mg/4 ml solution for injection  
Testosterone undecanoate  
For intramuscular injection only

**BESINS** HEALTHCARE  
By your side, for life

**NO COMPROMISE ON SYMPTOMS,  
CV AND PROSTATE HEALTH**

GLOBAL LEADER  
IN TRANSDERMAL  
TESTOSTERONE

**INSPIRES TRUST** via claims supported by robust data

**TRANSMITS EMPATHY** by being supportive and solutions-focused

**BUILDS CONFIDENCE** via BESINS expertise and experience

## BRAND PERSONA

### Who is Androgel® Man?

Androgel® man takes charge. He knows there's a challenge to be met regarding his low libido and is determined to tackle it head on. He wants the safest and most effective TTh because he's focused on men's health and well-being. He's an active man who wants to get back in the game and live his life to the full.

### Who is TESTOSTERONE BESINS Man?

TESTOSTERONE BESINS man is also a take-charge kind of guy. He's solutions-focused and demands flexibility, efficacy and safety at the best price for his TTh of choice. He wants a low-cost treatment option that fits in with his busy work schedule and full social life, so he's open to change and understands the "long-game" better than most.

# GLOBAL HCP CAMPAIGN

## GLOBAL VISUAL AID STRUCTURE

### Unmet need:

1. TD can be a game-changer for men
2. Why do men delay seeking help for TD?
3. Low libido is an early sign of TD
4. Identify low T comorbidities to get the TTh ball rolling
5. What are the benefits of TTh over time.

### Efficacy:

1. Androgel<sup>®</sup>: A new game plan for men with low libido
2. Androgel<sup>®</sup> tackles a range of TD symptoms

### Safety:

1. Androgel<sup>®</sup>: An unmatched profile in CV safety
2. Androgel<sup>®</sup>: An unmatched prostate safety profile

### Testing, dosing & monitoring:

1. Keeping an eye on the ball before & during TTh
2. Androgel<sup>®</sup> delivers predictable pharmacokinetics
3. Androgel<sup>®</sup> maintains optimal serum T levels
4. Know the score: flexible dose titration with Androgel<sup>®</sup>
5. Coaching men on the use of Androgel<sup>®</sup>

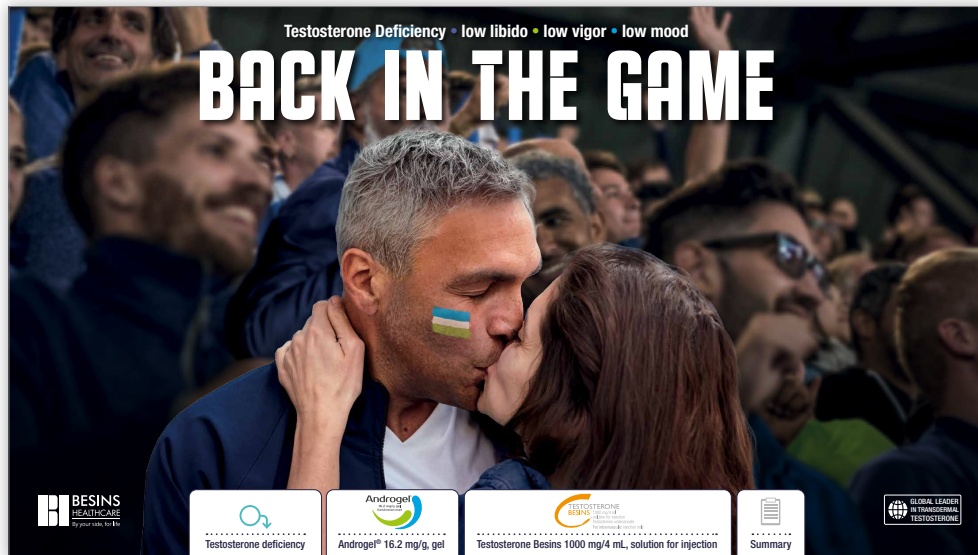
### Introducing Testosterone Besins:

1. The low-cost, long-acting TTh IM injectable preferred by patients
2. Testosterone Besins TTh IM injection provides gradual release of testosterone
3. Testosterone Besins dosing guide
4. Testosterone Besins method of administration
5. Keep men on side with Testosterone Besins

### Summary:

1. Team up against low libido with Androgel® & Testosterone Besins

### TRAVERSE clinical papers



**Page 1:** Team up against TD with AndroGel® and Testosterone Besins to get him back in the game. No compromise on symptoms and no compromise on CV & prostate health. BESINS Healthcare is the global leader in transdermal testosterone.

**NOTE:** There is a menu on this page so you can jump straight to the section most relevant to your sales call.

### TD CAN BE A GAME-CHANGER FOR MEN

■ MEN WANT TO TREAT THEIR LOW LIBIDO & OTHER KEY TD SYMPTOMS<sup>1</sup>

TD prevalence increases with age,<sup>2</sup> and profoundly disrupts men's lives<sup>3</sup>

- Prevalence of 2.1–12.3% in men aged 30–79 years<sup>4\*</sup>  
\*Depends on diagnostic criteria and the patient populations studied.
- Prevalence in obese men is 52% (BMI > 30 kg/m<sup>2</sup>) and 50% in men with T2DM<sup>6</sup>
- Fewer than 10% of men with TD receive TTh<sup>7</sup>

> A low rate of TD testing exists among older male patients, despite hypogonadal symptoms<sup>7</sup>

TD: Testosterone deficiency; TTh: Testosterone therapy.

Testosterone deficiency

AndroGel® 16.2 mg/g, gel

TESTOSTERONE BESINS 1000 mg/4 mL, solution for injection

Summary

**Page 2:** Hypogonadal men want to treat their low libido. TD prevalence increases with age, while prevalence in obese men and men with T2DM is 50%. Despite this, only 10% of men receive TTh. A low rate of TD testing on men exists, even on those with hypogonadal symptoms.

## WHY DO MEN DELAY SEEKING HELP FOR TD?

■ IN A SURVEY OF 90 MEN IN THE UK WITH DIAGNOSED TD, 55% WAITED 3-24 MONTHS, WHILE 35% WAITED FOR >2 YEARS BEFORE SEEKING ADVICE\*



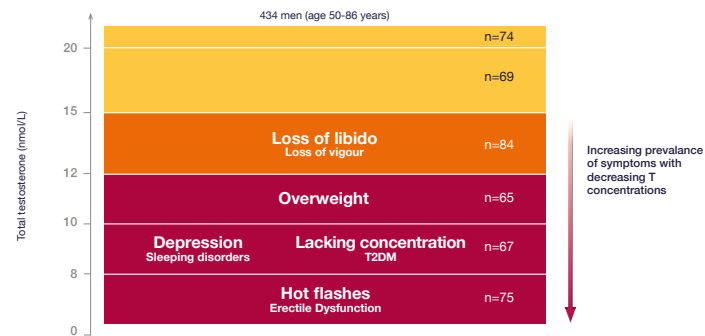
> Lack of awareness and embarrassment contribute to the underdiagnosis of TD\*



**Page 3:** A UK survey of 90 men diagnosed with TD found that over half waited up to 2 years, while over a third waited for over 2 years before seeing their doctor. Lack of awareness and shame seem to be the most common reasons for men not seeing their doctor about symptoms.

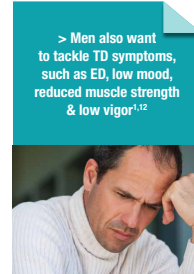
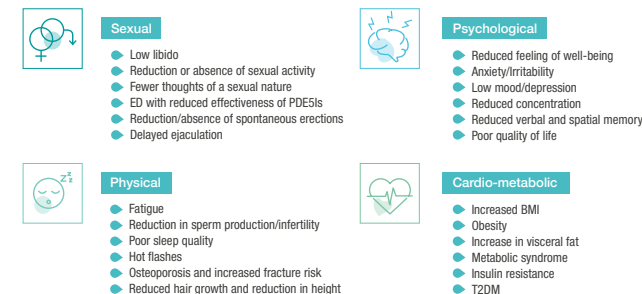
## LOW LIBIDO IS AN EARLY SYMPTOM OF TD<sup>10</sup>

■ CLINICAL FEATURES IN RELATION TO TESTOSTERONE LEVELS



## LOW LIBIDO IS AN EARLY SYMPTOM OF TD<sup>10</sup>

■ SYMPTOMS SUGGESTIVE OF TD<sup>11</sup>



BMI: Body mass index; ED: Erectile dysfunction; TD: Testosterone deficiency; T2DM: Type 2 diabetes mellitus



**Page 4 & 5:** Loss of libido is one of the earliest and commonest signs of TD. Other symptoms of hypogonadism follow, if TD isn't treated. A table of common symptoms are listed below the clinical features table. The callout reveals that men want to tackle these symptoms, despite a reluctance to see the doctor.



## IDENTIFY LOW T COMORBIDITIES TO GET THE TTH BALL ROLLING

■ MANY HYPOGONADAL MEN GO UNTESTED FOR LOW TESTOSTERONE DESPITE RELATED COMORBIDITIES:<sup>11,19</sup>



◆ **Metabolic diseases associated with insulin resistance**  
Obesity BMI>30kg/m<sup>2</sup>, metabolic syndrome, T2DM



◆ **Long-term medical treatments**  
Opioids, glucocorticoids, chemotherapy, radiotherapy, anticonvulsants, antipsychotics, HAART



◆ **CVD**  
Hypertension, CHD, cerebrovascular disease, CHF, AF



◆ **Andrological history**  
Cryptorchidism, testicular cancer, varicocele



◆ **Other chronic illnesses**  
COPD, renal failure, cirrhosis, anemia, osteoporosis, RA, HIV, cancer, depression, spinal cord injuries

Reference ranges for testosterone differ between laboratories. A lack of consensus can lead to under-diagnosis. Multiple societies now recommend using evidence-based action limits to diagnose TD<sup>13</sup>

> TEST & TREAT TO PREVENT THE ACCUMULATION OF WORSENING TD SYMPTOMS

AF: Atrial fibrillation; BMD: Bone mineral density; BMI: Body mass index; CHD: Coronary heart disease; CHF: Congestive heart failure; CVD: Cardiovascular disease; HAART: Highly active antiretroviral therapy; HIV: Human immunodeficiency virus; RA: Rheumatoid arthritis; TD: Testosterone deficiency; T2DM: Type 2 diabetes mellitus.

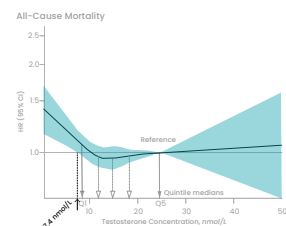


## IS THERE A LINK BETWEEN LOW T AND INCREASED ALL-CAUSE AND CV MORTALITY?

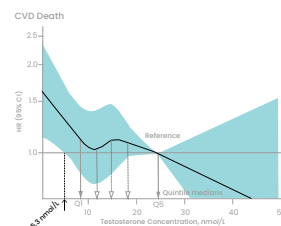
■ A 2024 META-ANALYSIS\* OF ~ 24,000 MEN<sup>23</sup> IDENTIFIED ASSOCIATIONS BETWEEN LOW T WITH ALL-CAUSE AND CV MORTALITY:<sup>23</sup>



◆ **Men with low testosterone <7.4 nmol/L (<213 ng/dL) had a higher risk of all-cause mortality, regardless of LH concentration**



◆ **Men with low testosterone <5.3 nmol/L (<153 ng/dL) had a higher risk of CVD death**



TTh FOR LOW T MAY HELP TACKLE MORE THAN JUST LOW LIBIDO

\*Observational study so causality cannot be determined.  
†Primarily Caucasian men. Results should be confirmed in studies with men of different ethnicities.  
‡Prospective cohort studies of community-dwelling men with sex steroids measured using mass spectrometry and at least 5 years of follow-up.  
ARIC: Atherosclerosis Risk in Communities; BHS: Basalton Health Study; CHS: Cardiovascular Health Study; CI: Confidence Interval; CV: Cardiovascular; CVD: Cardiovascular disease; EMAS: European Male Ageing Study; FHS: Framingham Heart Study; HMS: Health in Men Study; HR: Hazard ratio; LH: Luteinizing hormone; MALLS: Men Androgen Inflammation Lifestyle Environment and Stress; MGS: Osteoporotic Fractures in Men Study; SHIP: Study of Health in Pomerania; T: Testosterone; TTh: Testosterone therapy.



**Page 6:** Testing for TD is important to halt the progression of symptoms. However, even hypogonadal men that present with related comorbidities still go untested. Under diagnosis occurs because different laboratory assays use different reference ranges for low T. Testing and treating prevents the accumulation of worsening symptoms.

**Page 7:** A recent meta-analysis has found a possible link between low T and increased all-cause and CV mortality. The graphs show that men with testosterone levels <7.4 nmol/L had a higher risk of all-cause mortality, while men with levels <5.3 nmol/L had a higher risk of CV mortality. Use this page to highlight that TTh may help treat more than just low libido.

**WHAT ARE THE BENEFITS OF TTH OVER TIME?¹¹**

Time Period	Benefits
0-3 MONTHS	Improved libido (L1, Grade A) and general condition (asthenia)
0-6 MONTHS	Improved mood¹⁴ (Grade A)
6-12 MONTHS	Improved erectile & ejaculatory function (L1, Grade A). Reduction of fat mass and increase in lean mass (L1)
6 MONTHS - 2/3 YEARS	Increased BMD and bone strength (L2, Grade A)

**> MEN WITH TESTOSTERONE DEFICIENCY CAN EXPERIENCE SOME BENEFITS OF THERAPY AS EARLY AS 3 WEEKS¹¹,¹⁵**

BMD, Bone mineral density; Grade A, Established scientific proof; L1, Evidence Level 1 (studies with a high level of evidence: high-powered randomized controlled trials, meta-analysis of randomized controlled trials, decision analysis based on well-conducted studies); L2, Evidence Level 2 (intermediate level of evidence studies: underpowered randomized controlled trials, well-conducted non-randomized comparative studies, cohort studies); TTh, Testosterone Therapy.

Testosterone deficiency	Androgefil® 16.2 mg/g, gel	Testosterone Besins 1000 mg/4 mL, solution for injection	Summary
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**Page 8:** Prompt testing and treating provide benefits as soon as 3 months and lasts up to 3 years. The clinical evidence supporting the effect of TTh on symptom improvement is robust.

## ANDROGEL® - A NEW GAME PLAN FOR MEN WITH LOW LIBIDO

TRAVERSE | THE LARGEST EVER STUDY TO SHOW THAT ANDROGEL® EFFICACY ON LOW LIBIDO EXTENDS FOR UP TO 2 YEARS<sup>16</sup>

**TRAVERSE EFFICACY ON LOW LIBIDO**

Hypogonadal symptoms, sexual function, and sexual desire were significantly improved with AndroGel® vs. placebo (p<0.001) and were maintained for 2 years\*.

\*No effect on erectile dysfunction, however only 8.7% of patients were taking a PDE5 inhibitor.

### Significantly improved sexual function +

Estimated mean (95% CI) between-group difference

Months since randomization	Testosterone (n)	Placebo (n)	Estimated mean (95% CI) between-group difference
0	587	574	0
6	481	471	-2.7 (-5.1, -0.3)
12	388	394	-4.0 (-6.8, -1.3)
24	307	288	-3.4 (-6.4, -0.3)

### Significantly improved sexual desire +

Estimated mean (95% CI) between-group difference

Months since randomization	Testosterone (n)	Placebo (n)	Estimated mean (95% CI) between-group difference
0	587	574	0
6	484	473	-3.9 (-5.8, -1.9)
12	390	394	-3.3 (-5.5, -1.1)
24	308	288	-3.3 (-5.5, -1.1)

> AndroGel® helps men with low libido get back in the game

TRAVERSE Sexual Function Substudy Design +

CI: Confidence interval; IIEF-Q: The Hypogonadism Impact of Symptoms Questionnaire Short Form; IIEF-S: International Index of Erectile Function; PDQ-4: The Personality Diagnostic Questionnaire Version 4

Testosterone deficiency

AndroGel® 16.2 mg/g, gel

Testosterone Besins 1000 mg/4 mL, solution for injection

Summary

**Page 9:** The first efficacy page reveals the results of the TRAVERSE study. A brief overview of the study design is followed by the significant results on improved libido (sexual function and sexual desire), which are maintained for 2 years.

**Significantly improved sexual function**

Estimated mean (95% CI) between-group difference

Months since randomization	Testosterone (n)	Placebo (n)	Estimated mean (95% CI) between-group difference
0	587	574	0
6	481	471	-2.7 (-5.1, -0.3)
12	388	394	-4.0 (-6.8, -1.3)
24	307	288	-3.4 (-6.4, -0.3)

Omnibus test p=0.019

Page 10

**Significantly improved sexual desire**

Estimated mean (95% CI) between-group difference

Months since randomization	Testosterone (n)	Placebo (n)	Estimated mean (95% CI) between-group difference
0	587	574	0
6	484	473	-3.9 (-5.8, -1.9)
12	390	394	-3.3 (-5.5, -1.1)
24	308	288	-3.3 (-5.5, -1.1)

Omnibus test p=0.001

Page 11

**TRAVERSE Sexual Function Substudy Design**

Phase 4, multicenter, randomized, double-blind, placebo-controlled, trial in 1,161 men\* with low libido.

\*57 randomized to receive 1.62% 10 transdermal AndroGel® and 574 to placebo gel.

**Primary endpoint:**  
Change from baseline in sexual activity score (assessed via PDQ-4)

**Secondary endpoints:**

- Hypogonadal symptoms (assessed via HS-Q composite score)
- Men with low libido assessed via De Rogatis Interview for Sexual Functioning – Desire Score <20
- Erectile function (assessed via IIEF-S)

Page 12

## ANDROGEL® TACKLES A RANGE OF TD SYMPTOMS

■ ANDROGEL® IS THE TTH OF CHOICE BECAUSE IT:

- Provides significant correction of anemia\* in hypogonadal men for up to 48 months vs. placebo (P=0.002)<sup>17</sup>
- Provides significant mood improvements\* (n=1,308; P=0.001) vs. placebo (n=1,335) for up to 24 months as measured by HIS-Q mood domain score<sup>18</sup>
- Provides significant improvements in depressive symptoms\* in men as assessed by HIS-Q mood domain score at 24 months (n=1,297; P=0.003) vs. placebo (n=1,226)<sup>18</sup>
- Significantly increases lean body mass\* (n=123; P=0.0001) from Baseline and throughout treatment<sup>19</sup>
- Provides a gradual and progressive increase in BMD\* of the hip (n=123; P=0.0004) and spine (n=123; P=0.0001)<sup>19</sup>

> Team up with AndroGel® to manage TD symptoms

\*AndroGel® 1.62%; Testosterone Gel 1.0%  
BMD: Bone mineral density; HIS-Q: The Hypogonadism Impact of Symptoms Questionnaire Short Form; TD: Testosterone deficiency; TTh: Testosterone therapy.

Testosterone deficiency | AndroGel® 16.2 mg/g, gel | Testosterone Besins 1000 mg/4 mL, solution for injection | Summary

**Page 13:** The second efficacy page shows how AndroGel® not only successfully tackles low libido, but also has a significant positive effects across a range of other hypogonadal symptoms.

## ANDROGEL® - AN UNMATCHED PROFILE IN CV SAFETY<sup>20</sup>

TRAVERGE | ANDROGEL® IS THE FIRST AND ONLY TTH BRAND WITH SIGNIFICANT LONG-TERM CV SAFETY DATA<sup>20</sup>

■ TRAVERGE RESULTS

Proven CV safety\* (n=2,601; P<0.001) vs. placebo (n=2,603) over an average treatment duration of 22 months and follow-up of 33 months<sup>20</sup>

	HR (95% CI)	TTh (N=2596) number of patients (n)	Placebo (N=2602) number of patients (n)
<b>Primary CV composite safety endpoint: MACE</b>	0.96 (0.78-1.17)*	182 (7.0)	190 (7.3)
<b>Secondary CV composite safety endpoint</b>	1.02 (0.86-1.21)	269 (10.4)	284 (10.1)
• Death from CV causes	0.84 (0.63-1.12)	87 (3.4)	103 (4.0)
• Non-fatal MI	1.10 (0.78-1.56)	68 (2.6)	82 (2.4)
• Non-fatal stroke	0.94 (0.60-1.49)	36 (1.4)	38 (1.5)
• Coronary revascularisation	1.20 (0.95-1.53)	144 (5.5)	121 (4.6)

\*p<0.001 for non-inferiority of TTh vs. placebo

> Make CV safety your priority with AndroGel®

TRAVERGE CV Study Design

\*AndroGel® 1.62%  
CI: Confidence interval; CV: Cardiovascular; CVD: Cardiovascular disease; MACE: Major adverse cardiovascular event; MI: Myocardial infarction; PBO: Placebo; TTh: Testosterone therapy.

Testosterone deficiency | AndroGel® 16.2 mg/g, gel | Testosterone Besins 1000 mg/4 mL, solution for injection | Summary

**Page 14:** The first safety page introduces the positive CV health results from TRAVERGE. A brief overview of the CV study is presented. The results demonstrate that AndroGel® is the first and only transdermal TTh brand to provide such robust CV safety data over 22 months of treatment and 33 months of follow up.

## ANDROGEL® - AN UNMATCHED PROFILE IN CV SAFETY

TRAVERGE CV Study Design

- Phase 4, multicenter, randomized, double-blind, placebo-controlled, non-inferiority, event-driven trial
- 5,246 men aged 45-80 years with hypogonadal symptoms and pre-existing CVD/elevated CV risk
- Two fasting testosterone levels <10.4 nmol/L (<300 ng/dL)

**Primary composite endpoint:**  
First occurrence of MACE (death from CV causes, non-fatal MI or non-fatal stroke)

**Secondary composite endpoint:**  
First occurrence of death from CV causes, non-fatal MI, non-fatal stroke, or coronary revascularization

Testosterone deficiency | AndroGel® 16.2 mg/g, gel | Testosterone Besins 1000 mg/4 mL, solution for injection | Summary

Page 15

## ANDROGEL®: AN UNMATCHED PROSTATE SAFETY PROFILE<sup>21</sup>

**TRVERSE** | ANDROGEL® IS THE FIRST AND ONLY TTh BRAND WITH SIGNIFICANT LONG-TERM PROSTATE SAFETY DATA<sup>21</sup>

**TRVERSE RESULTS**

Proven prostate cancer safety\* over a mean of 33 months of follow-up<sup>21</sup>

End point	No. (%) participants experiencing events		Hazard ratio (95% CI): TTh vs. placebo
	TTh (N=2596)	Placebo (N=2602)	
<b>Primary</b>			
High-grade prostate cancer	5 (0.19)	3 (0.12)	1.62 (0.39-6.77)
<b>Secondary</b>			
Any prostate cancer	12 (0.46)	11 (0.42)	1.07 (0.47-2.42)
Acute urinary retention	20 (0.77)	16 (0.61)	1.25 (0.65-2.41)
Invasive procedure for BPH	23 (0.89)	12 (0.46)	1.91 (0.95-3.84)
Prostate biopsy	16 (0.62)	14 (0.54)	1.13 (0.55-2.31)
New pharmacologic treatment	101 (3.89)	87 (3.34)	1.16 (0.87-1.54)

**> Make prostate safety your priority with AndroGel®**

**TRVERSE Prostate Safety Substudy Design**

\*AndroGel 1.62%  
BPH: Benign prostatic hyperplasia; CI: Confidence interval; CV: Cardiovascular; CVD: Cardiovascular disease; LUTS: Lower urinary tract symptoms; MI: Myocardial infarction; PBO: Placebo; PSA: Prostate specific antigen; TTh: Testosterone therapy.

Testosterone deficiency | AndroGel® 16.2 mg/g gel | Testosterone Besins 1000 mg/4 mL solution for injection | Summary

**Page 16:** The second safety page introduces the positive prostate health results from TRVERSE. A brief overview of the prostate study is presented. Again, AndroGel® is the first and only transdermal TTh brand to provide long-term prostate safety data.

**TRVERSE Prostate Safety Substudy Design**

This placebo-controlled, double-blind randomized clinical trial enrolled 5246 men (aged 45-80 years) from 316 US trial sites who had 2 testosterone concentrations less than 300 ng/dL, hypogonadal symptoms, and cardiovascular disease (CVD) or increased CVD risk. Men with a history of prostate cancer, PSA concentrations >3.0 ng/mL, and/or PPS >19 were excluded.

**Primary endpoint:**  
Compare the effects of TTh vs. placebo on the incidence of adjudicated\* high-grade prostate cancer (Gleason grade 4+ > 3 on biopsy).

**Secondary endpoint:**  
Compare effects of TTh vs. placebo on the incidence of:

- Any prostate cancer
- Acute urinary retention
- Invasive prostate surgical procedure for BPH

Compare change in TRT vs. placebo in:

- PSA
- Prostate biopsy†
- Initiation of new pharmacologic treatment for LUTS

\*Gleason grade 4+ prostate cancer as determined by a blinded Prostate Adjudication Committee.  
†Prostate biopsy requires prior confirmation by a blinded Prostate Adjudication Committee.  
\*Gleason grade 4+ prostate cancer as determined by a blinded Prostate Adjudication Committee.  
†Prostate biopsy requires prior confirmation by a blinded Prostate Adjudication Committee.

Testosterone deficiency | AndroGel® 16.2 mg/g gel | Testosterone Besins 1000 mg/4 mL solution for injection | Summary

**Page 17**

## KEEPING AN EYE ON THE BALL BEFORE & DURING TTh

**WHEN IS TTh WITH ANDROGEL® INDICATED?**

- TD is clearly demonstrated by clinical signs and symptoms and confirmed by 2 separate measurements of serum testosterone<sup>22</sup>
- AndroGel® 1.62% should only be prescribed if hypogonadism has been diagnosed and other conditions that could mimic TD symptoms have been excluded<sup>22</sup>
- Patients with clinical features and 2 consecutive morning fasting levels <8 nmol/L are likely to have hypogonadism<sup>23</sup>
- Morning fasted levels of 8–12 nmol/L\* may be seen in eugonadal or hypogonadal men, and so require careful clinical correlation<sup>23</sup>

\*Total testosterone >12 nmol/L is unlikely to represent hypogonadism.

**MONITORING OF ANDROGEL® TTh<sup>22</sup>**


Monitoring frequency	At 3, 6, and 12 months of treatment then annually	
Clinical exam	Digital rectal exam Manual breast exam (sensitivity, presence of gynecomastia, nodules/lumps)	
Laboratory testing	Serum testosterone Monitoring schedule depends on TTh formulation: • Transdermal route: Test prior to application • IM route: Test prior to the next injection to measure trough level	
	PSA	Men with a baseline of 3 ng/mL or above should be tested to exclude prostate cancer
	Other	Hematocrit, hemoglobin, liver function and lipid profile
Other monitoring	BMD Monitor in men with abnormal BMD prior to initiating TTh. Repeat DEXA scanning is recommended after 1-2 years of TTh	

BMD: Bone mineral density; IM: Intramuscular; PSA: Prostate specific antigen; TTh: Testosterone therapy.


Testosterone deficiency | AndroGel® 16.2 mg/g gel | Testosterone Besins 1000 mg/4 mL solution for injection | Summary

**Page 18:** The first testing/monitoring page introduces when TTh with AndroGel® is indicated. The fourth bullet is taken from a consensus statement paper shown in the clinical update table on Pages 10 and 11 of this document regarding the **standardization of the biochemical confirmation of adult male hypogonadism.**

## ANDROGEL® DELIVERS PREDICTABLE PHARMACOKINETICS<sup>22</sup>




- Diffusion of testosterone into the general circulation at relatively constant rates over a 24-hour period




- Increase in testosterone levels from the first hour after application, reaching steady state from Day 2
  - No peak in plasma concentrations


**A QUICK RETURN TO BASELINE TESTOSTERONE LEVELS IF REQUIRED<sup>22</sup>**  
\*Return to baseline testosterone after ~72-96 hours




Testosterone deficiency



AndroGel® 16.2 mg/g, gel



Testosterone Besins 1000 mg/4 mL, solution for injection



Summary

**Page 19:** If required on the call, you can showcase that AndroGel® TTh delivers predictable diffusion of testosterone at constant rates over 24 hours. You can also explain that testosterone levels reach steady state from Day 2 of treatment with no peak in plasma concentrations. A rapid return to baseline testosterone levels can also be achieved when AndroGel® treatment is withdrawn. If the HCP requires further clinical evidence, go to Page 20 of the Detail Aid to cover the Phase III pivotal trial.

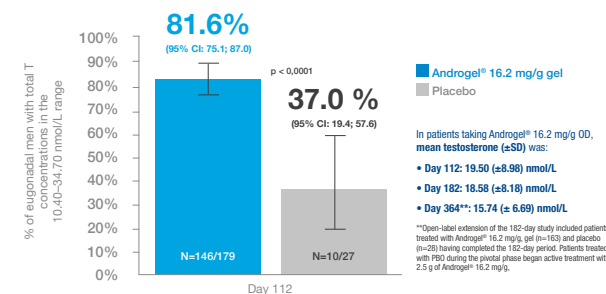
## CLINICAL STUDY SPOTLIGHT: ANDROGEL MAINTAINS OPTIMAL SERUM T LEVELS<sup>25</sup>

### SERUM TESTOSTERONE IN THE NORMAL RANGE\* >8/10 MEN

Pivotal, placebo-controlled, multicenter, 182-day, phase III double-blind study in 274 hypogonadal men aged 18–80 years with T levels <10.4nmol/L (<300ng/dL) measured by 2 separate assays

**Primary endpoint:**  
Percentage of men with total serum T within normal range\* for eugonadal men  
\*normal range 10.4–34.7 nmol/L at the end of the 112-day treatment

### PHASE 3 PIVOTAL STUDY RESULTS<sup>25</sup>




Treatment	% of eugonadal men with total T concentrations in the 10.40–34.70 nmol/L range	95% CI
AndroGel® 16.2 mg/g gel	81.6%	75.1, 87.0
Placebo	37.0%	19.4, 57.6


**In patients taking AndroGel® 16.2 mg/g OD, mean testosterone (±SD) was:**

- Day 112: 19.50 (±8.98) nmol/L
- Day 182: 18.58 (±8.18) nmol/L
- Day 364<sup>\*\*\*</sup>: 15.74 (± 6.69) nmol/L


\*\*Open-label extension of the 182-day study included patients treated with AndroGel® 16.2 mg/g gel (n=162) and placebo (n=28) having completed the 182-day period. Patients treated with PBO during the pivotal phase began active treatment with 2.2 g of AndroGel® 16.2 mg/g.




Testosterone deficiency



AndroGel® 16.2 mg/g, gel



Testosterone Besins 1000 mg/4 mL, solution for injection



Summary

**Page 20:** Key pivotal phase III study outlining the serum T levels maintained by AndroGel® in hypogonadal males to further support the pharmacokinetic claims made on Page 19 of the Detail Aid.

### CLINICAL STUDY SPOTLIGHT: ANDROGEL MAINTAINS OPTIMAL SERUM T LEVELS<sup>25</sup>

**SERUM TESTOSTERONE IN THE NORMAL RANGE\* >8/10 MEN**

Pivotal, placebo-controlled, multicenter, 182-day, phase III double-blind study in 274 hypogonadal men aged 18–80 years with T levels <10.4nmol/L (<300ng/dL) measured by 2 separate assays

**Primary endpoint:**  
Percentage of men with total serum T within normal range\* for eugonadal men  
\*normal range 10.4–34.7 nmol/L at the end of the 112-day treatment

**PHASE 3 PIVOTAL STUDY RESULTS<sup>25</sup>**

Treatment	% of eugonadal men with total T concentrations in the 10.40-34.70 nmol/L range	95% CI	N
AndroGel® 16.2 mg/g gel	81.6%	75.1; 87.0	146/179
Placebo	37.0%	19.4; 57.6	10/27

In patients taking AndroGel® 16.2 mg/g OD, mean testosterone (±SD) was:

- Day 112: 19.50 (±8.98) nmol/L
- Day 182: 18.58 (±8.18) nmol/L
- Day 364<sup>\*\*</sup>: 15.74 (± 6.69) nmol/L

\*\*Open-label extension of the 182-day study included patients treated with AndroGel® 16.2 mg/g gel (n=163) and placebo (n=20) having completed the 182-day period. Patients treated with PBO during the pivotal phase began active treatment with 2.5 g of AndroGel® 16.2 mg/g.

Testosterone deficiency

AndroGel® 16.2 mg/g, gel

Testosterone Besins 1000 mg/4 mL, solution for injection

Summary

**Page 21:** The flexible dosing titration visual for AndroGel® TTh presents the number of pump actuations required to deliver the optimal amount of testosterone to the skin – from the lowest dose to the initial recommended dose and up to the maximum recommended dose. This links to the copy below the visual, which you can use to emphasize and expand on AndroGel® individualized dosing. You can also explain when AndroGel® treatment should stop.

### COACHING MEN ON THE USE OF ANDROGEL<sup>22</sup>

**AndroGel® administration method**

**Avoiding accidental transfer of testosterone<sup>22</sup>**

**IF ACCIDENTAL TRANSFER OCCURS:**

- Wash the affected area with soap as soon as possible
- Report any sign of testosterone transfer, such as acne or hair loss, to a doctor

\*AndroGel® contains ethanol which can cause a burning sensation on damaged skin. It may also be flammable until the product completely dries.

Testosterone deficiency

AndroGel® 16.2 mg/g, gel


Testosterone Besins 1000 mg/4 mL, solution for injection

Summary

**Page 22:** The infographic shows how to apply AndroGel® and avoid its transference to others.

## INTRODUCING NEW TESTOSTERONE BESINS

**THE LOW-COST, LONG-ACTING TTh IM INJECTABLE PREFERRED BY PATIENTS<sup>24,26,27</sup>**




**TESTOSTERONE BESINS**  
1000 mg/4 mL solution for injection  
Testosterone undecanoate  
For intramuscular injection only

**WHY CHOOSE TESTOSTERONE BESINS?**


- It provides a more cost-effective solution than the Reference Brand for pricing and reimbursement<sup>27</sup>
- It helps reduce progression from pre-diabetes to T2DM in combination with lifestyle improvements<sup>28</sup>
- It offers patients the potential for a limited number of injections per year<sup>25</sup>
- It is the treatment of choice after initiation with AndroGel<sup>®25</sup>
- It significantly improves low libido, fatigue, low mood, and low vigor<sup>28,29</sup>
- It is the market leader among TTh IM injectables worldwide<sup>31</sup>

> TESTOSTERONE BESINS offers men an alternative delivery route post AndroGel<sup>®</sup> initiation


IM: Intramuscular; TD: Testosterone deficiency; TTh: Testosterone therapy; T2DM: Type 2 diabetes mellitus.




Testosterone deficiency



AndroGel<sup>®</sup> 16.2 mg/g, gel



Testosterone Besins 1000 mg/4 mL, solution for injection



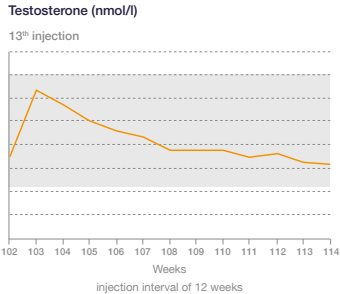
Summary

**Page 23:** This page introduces low-cost, patient preferred Testosterone Besins and showcases the product's main benefits.

## TESTOSTERONE BESINS IM INJECTION PROVIDES GRADUAL RELEASE OF TESTOSTERONE<sup>32</sup>

**ADVANTAGES OF TESTOSTERONE BESINS OIL-BASED INTRAMUSCULAR INJECTION:**

- No first-pass hepatic effect
- Gradual release and cleavage of component via testosterone and undecanoic acid hepatic esterases
- Provides increase in serum testosterone levels beyond baseline values from Day 1




Testosterone (nmol/l)  
13<sup>th</sup> injection

Weeks  
injection interval of 12 weeks


The figure shows the serum testosterone concentration after the 13<sup>th</sup> injection of long-term therapy with testosterone undecanoate<sup>32</sup>

> TESTOSTERONE BESINS delivers stable testosterone levels for injection intervals up to 3 months<sup>32</sup>


IM: Intramuscular




Testosterone deficiency



AndroGel<sup>®</sup> 16.2 mg/g, gel



Testosterone Besins 1000 mg/4 mL, solution for injection



Summary

**Page 24:** Testosterone Besins gradual release of testosterone and pharmacokinetics at each injection stage to deliver stable T levels for up to 3 months.



## TESTOSTERONE BESINS DOSING GUIDE

**■ MAINTENANCE AND INDIVIDUALIZATION OF TREATMENT<sup>24</sup>**  
Serum testosterone levels should be measured before starting treatment and during treatment

Weeks of treatment

Careful monitoring of serum testosterone levels is required during maintenance of treatment. It is advisable to measure testosterone serum levels regularly. Measurements should be performed at the end of an injection interval and clinical symptoms considered for individualization of therapy. These serum levels should be within the lower third of the normal range. Serum levels below normal range would indicate the need for shorter injection intervals. In case of high serum levels, an extension of the injection interval may be considered.

**> TESTOSTERONE BESINS may improve adherence due to a limited number of injections per year<sup>25</sup>**

IM, Intramuscular

Testosterone deficiency	Androge <span style="color: green;">l</span> <sup>®</sup> 16.2 mg/g, gel	TESTOSTERONE BESINS 1000 mg/4 mL, solution for injection	Summary
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**Page 25:** Testosterone Besins may help improve adherence during maintenance and treatment individualization, which is why it is the patient-preferred route. Also, that testosterone should be measured before and during treatment.

## TESTOSTERONE BESINS METHOD OF ADMINISTRATION<sup>24</sup>

**1G/4 mL vial**

1.0 G TESTOSTERONE UNDECANOATE  
▶ 631.5 mg of testosterone

Shelf life: 2 years  
Excipients: 2000 mg benzyl benzoate per bottle, refined castor oil 1,180 mg

**IM injection only**

- Use immediately after opening
- Inject deep into the gluteal muscle, following the usual precautions for IM injections
- To be administered very slowly (>2 minutes)

**2 years**

**2 min**

Pulmonary microembolism caused by oil-based excipient may, in rare cases, cause the following: cough; dyspnea; malaise; hyperhidrosis; chest pain; dizziness; paresthesias; or syncope. These reactions can occur during or immediately after injection and are reversible. The patient must therefore be subject to regular monitoring during and immediately after each injection of TESTOSTERONE BESINS 1000 mg/4 mL in order to be able to recognize as quickly as possible the possible signs and symptoms of a pulmonary micro-embolism due to oily solutions. Treatment is usually supportive, e.g. by administration of supplemental oxygen. Suspected cases of anaphylactic reactions after injection of NEBIDO<sup>®</sup> 1000 mg/mL have been reported. This speciality is a generic of NEBIDO<sup>®</sup>, 1000 mg/4 mL, solution for injection.


Testosterone deficiency	Androge <span style="color: green;">l</span> <sup>®</sup> 16.2 mg/g, gel	TESTOSTERONE BESINS 1000 mg/4 mL, solution for injection	Summary
-------------------------	--	--	---------

**Page 26:** Use this page to show the doctor the optimal method of injecting Testosterone Besins. The left side of the page shows the basic ingredients and properties of the product, while the right side provides brief guidance on the injection approach. The copy below details contraindications that may occur during administration.


## KEEP MEN ON SIDE WITH TESTOSTERONE BESINS

■ MAINTAIN TTH ADHERENCE & COMPLIANCE BY HAVING THE SWITCH CONVERSATION WITH PATIENTS

INITIATE WITH







AT 12 MONTH REVIEW CONSIDER



> BESINS HEALTHCARE TAILORED SOLUTION FOR ALL YOUR TD PATIENTS<sup>®</sup>

IM, Intramuscular; QD, Once-daily; TD, Testosterone deficiency; TTh, Testosterone therapy

 Testosterone deficiency	 Androgel <sup>®</sup> 16.2 mg/g, gel	 Testosterone Besins 1000 mg/4 mL, solution for injection	 Summary
--	---	---	--

**Page 27:** Use this page to help the doctor understand that TTh compliance can be maintained by having a conversation with the patient about moving over to an injectable testosterone, if they would prefer it.

## TEAM UP AGAINST LOW LIBIDO WITH ANDROGEL<sup>®</sup> & TESTOSTERONE BESINS



**Proven efficacy on low libido over 24 months<sup>16</sup>**  
**Unmatched long-term CV & prostate safety<sup>20,21</sup>**



**World-leading, patient-preferred TTh injectable<sup>26</sup>**


> GET HIM BACK IN THE GAME WITH ANDROGEL<sup>®</sup> & TESTOSTERONE BESINS

This information does not replace the official SmPC approved in each country. Please consult the full prescribing information in your country for more details. Any side effects/adverse events should be reported to [pharmacovigilance@besins-healthcare.com](mailto:pharmacovigilance@besins-healthcare.com)


 Testosterone deficiency	 Androgel <sup>®</sup> 16.2 mg/g, gel	 Testosterone Besins 1000 mg/4 mL, solution for injection	 Summary
--	---	---	--


**Page 28:** The final page summarizes the main benefits of both Androgel<sup>®</sup> and Testosterone Besins to finish the sales call: Androgel<sup>®</sup>'s proven efficacy on low libido; unmatched CV and prostate safety; and world-leading Testosterone Besins' status as the patient-preferred TTh injectable. We end with the message underlying the campaign creative call-to-action: "Get him back in the game".

## TEAM UP AGAINST TESTOSTERONE DEFICIENCY



SCAN QR CODE TO ACCESS FULL CLINICAL PAPERS





**■ TRAVERSE CV SAFETY**  
Cardiovascular safety of testosterone-replacement therapy  
Lincoff AM, et al. *N Engl J Med* 2023; doi: 10.1056/NEJMoa2215025.  
*QR code active until end of Dec 2024.*




**■ TRAVERSE PROSTATE SAFETY**  
Prostate safety events during testosterone replacement therapy in men with hypogonadism  
Bhasin S, et al. *JAMA Netw Open* 2023;6(12):e2348692.

**■ TRAVERSE SEXUAL FUNCTION**  
Effect of testosterone replacement therapy on sexual function and hypogonadal symptoms in men with hypogonadism  
Pencina KM, et al. *J Clin Endocrinol Metab* 2023; doi: 10.1210/clinem/dgad484.

1. Tsujimura A, et al. *World J Mens Health*. 2013;31(2):126-135.
2. Araujo AB, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2007;92(11):4241-4247.
3. Traish AM, et al. *The American Journal of Medicine*. 2011;124(7):578-587.
4. European Male Aging Study (EMAS). *New England Journal of Medicine*. 2010;363(2):123-135.
5. Araujo AB, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2004;89(12):5920-5926.
6. Khara M, et al. *The Journal of Sexual Medicine*. 2016; 13:1767-1804.
7. Tostian JL, et al. *Nature Clinical Practice Urology*. 2008;5:388-396.
8. Edwards D. Meeting Report. British Society for Sexual Medicine. October 2016.
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10. Zitzmann M, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2006;91(11):4335-4343.
11. Burtle C, et al. *Progrès en urologie*. 2021;31:458-476.
12. Depressive Syndromes in Men With Hypogonadism in the TRAVERSE Trial: Response to Testosterone-Replacement Therapy *The Journal of Clinical Endocrinology & Metabolism*. 2024, 00, 1-13 - 11 January 2024, 11 January 2024.
13. Al-Sharif A, et al. *Endocrinology & Metabolism*. 2020;35:526-540.
14. Livingston M, et al. *International Journal of Clinical Practice*. 2020;74:e13607.
15. Snyder PJ, et al. *New England Journal of Medicine*. 2016;374(7):611-624.
16. Pencina KM, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2023;109(2):569-580.
17. Pencina KM, et al. *JAMA*. 2023;6(10):e2340030. DOI:10.1001/2024.
18. Bhasin S, et al. *J Clin Endocrinol Metab* 2024
19. Wang C, et al. *The Journal of Clinical Endocrinology & Metabolism*. 2004;89(5):2085-2088.
20. Lincoff AM, et al. *New England Journal of Medicine*. 2023; doi: 10.1056/NEJMoa2215025.
21. Bhasin S et al. *JAMA Network Open*. 2023;6(12):e2348692.
22. Androge<sup>®</sup> Summary of Product Characteristics.
23. Jayaraman DN, et al. *Clinical Endocrinology*. 2021;1-20.
24. TESTOSTERONE BESINS Summary of Product Characteristics.
25. Kaufman JM, et al. *Journal of Sexual Medicine*. 2011;8:2079-2089.
26. Knapp JR, et al. *J Sex Med*. 2014;11(2):559-562.
27. Data on File. Besins.
28. Morales A, et al. *The Aging Male*. 2006;9(4):221-227.
29. Wolf J, et al. *The Aging Male*. 2017;20(4):225-234.
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31. IQVIA Data on File. Besins.
32. Von Eckardstein S, Weischlag E. Treatment of male hypogonadism with testosterone undecanoate injected at extended intervals of 12 weeks: a phase 8 study. *J Androl*. 2002;23(3):419-425.
33. Yeap BB, et al. *Ann Intern Med*. 2024; DOI:10.7326/M232781.



Testosterone deficiency



Androge<sup>®</sup> 16.2 mg/g, gel



Testosterone Besins 1000 mg/4 mL, solution for injection



Summary

**Page 29:** This page can be directly accessed from the button menu on the front page. Use it to share the TRAVERSE clinical papers with the HCPs. It also contains the reference list for all claims in the detail aid.

35

## AndroGel® and Testosterone Besins Digital Visual Aid



## Androgel® and Testosterone Besins Press Ad

Testosterone Deficiency • low libido • low vigor • low mood

# BACK IN THE GAME

**Androgel**  
16.2 mg/g gel  
(testosterone)

**TESTOSTERONE  
BESINS**  
1000 mg/4 mL  
solution for injection  
testosterone undecanoate  
For intramuscular injection only

**BESINS**  
HEALTHCARE  
By your side, for life

**NO COMPROMISE ON SYMPTOMS,  
CV AND PROSTATE HEALTH**

**GLOBAL LEADER  
IN TRANSDERMAL  
TESTOSTERONE**

Testosterone Deficiency • low libido • low vigor • low mood

# BACK IN THE GAME

**Androgel**  
16.2 mg/g gel  
(testosterone)

**TESTOSTERONE  
BESINS**  
1000 mg/4 mL  
solution for injection  
testosterone undecanoate  
For intramuscular injection only

**BESINS**  
HEALTHCARE  
By your side, for life

**NO COMPROMISE ON SYMPTOMS,  
CV AND PROSTATE HEALTH**

**GLOBAL LEADER  
IN TRANSDERMAL  
TESTOSTERONE**

Alternative

Testosterone Deficiency • low libido • low vigor • low mood

# BACK IN THE GAME

**Androgel**  
16.2 mg/g gel  
(testosterone)

**TESTOSTERONE  
BESINS**  
1000 mg/4 mL  
solution for injection  
testosterone undecanoate  
For intramuscular injection only

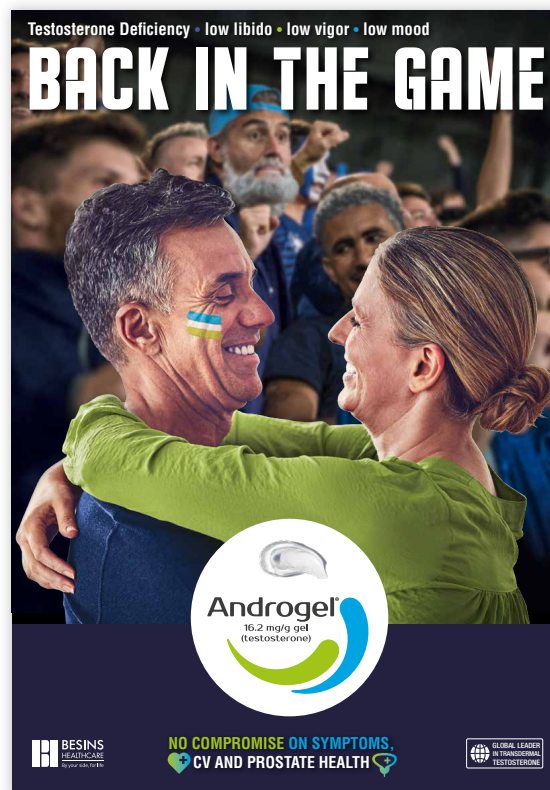
**BESINS**  
HEALTHCARE  
By your side, for life

**NO COMPROMISE ON SYMPTOMS,  
CV AND PROSTATE HEALTH**

**GLOBAL LEADER  
IN TRANSDERMAL  
TESTOSTERONE**

Alternative

## Androgel® Press Ad

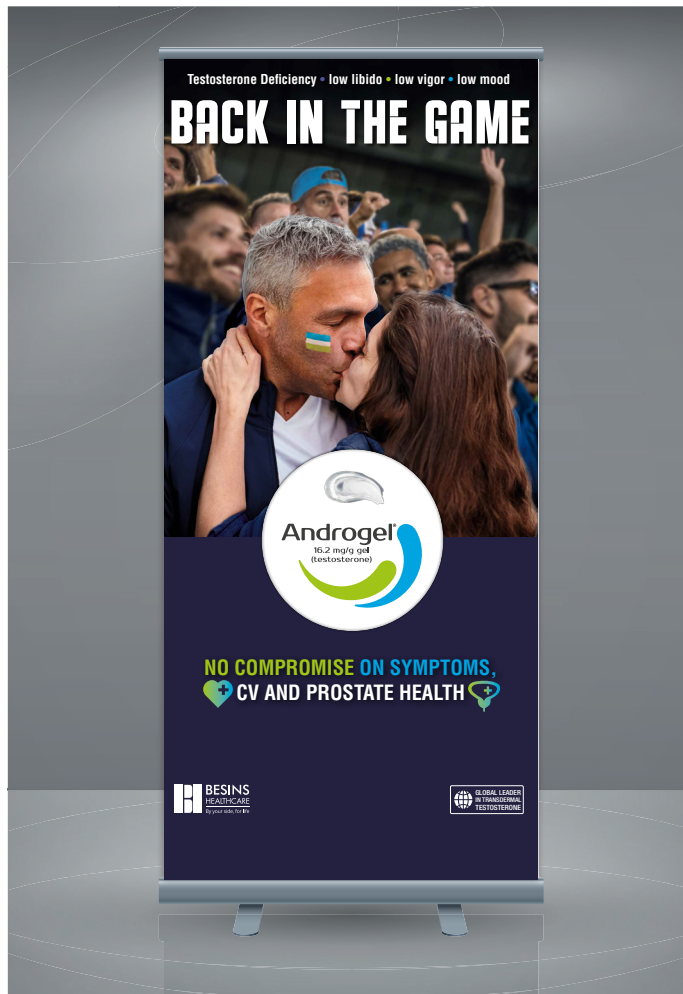


Alternative



Alternative

## Androgel<sup>®</sup> Rollup Banner



## Androgel<sup>®</sup> and Testosterone Besins Rollup Banner



## Androgel® Dosing Card

**Androgel®**  
16.2 mg/g gel  
(testosterone)

Gel

Testosterone Deficiency • low libido • low vigor • low mood  
**BACK IN THE GAME**

Proven efficacy on low libido over 24 months<sup>1</sup>  
Unmatched long-term CV & prostate safety<sup>2,3</sup>

TRAVERSE

ACCESS FULL CLINICAL PAPERS

CV SAFETY  
Study of testosterone-replacement therapy  
JAMA 2023; doi: 10.1096/NL.M10215025.  
17 Dec 2024.

PROSTATE SAFETY  
Study of testosterone-replacement therapy  
during testosterone replacement therapy  
JAMA Netw Open 2023;6(12):e2348892.

BESINS HEALTHCARE  
By your side, for life

## Testosterone Besins Dosing Card

**NEW**

**TESTOSTERONE**  
BESINS  
1000 mg/4 ml  
solution for injection  
Testosterone undecanoate  
For intramuscular injection only

Intramuscular injection

Solution for injection,  
1 x 4 ml vial.  
Intramuscular use.

World leading,  
patient-preferred TTh injectable<sup>1</sup>

Testosterone Deficiency • low libido • low vigor • low mood  
**BACK IN THE GAME**

AMUSCULAR INJECTION

NEW

BESINS HEALTHCARE  
By your side, for life



## Power Point Template

Testosterone Deficiency - low libido - low vigor - low mood

# BACK IN THE GAME

**NO COMPROMISE ON SYMPTOMS.**  
CV AND PROSTATE HEALTH

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

# BACK IN THE GAME

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

TITLE SCREEN  
NEUTRAL

BESINS HEALTHCARE

TITLE OF THE SLIDE

TEXT SCREEN

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

TITLE OF THE SLIDE

TEXT SCREEN

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

## Power Point Template option

Testosterone Deficiency - low libido - low vigor - low mood

# BACK IN THE GAME

**NO COMPROMISE ON SYMPTOMS.**  
CV AND PROSTATE HEALTH

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

Testosterone Deficiency - low libido - low vigor - low mood

# BACK IN THE GAME

**Androgel**  
10.2 mg/g gel (testosterone)

**TESTOSTERONE**  
BESINS

BESINS HEALTHCARE

## TRAVERSE Page Leave Behind





## IV. GLOBAL BRAND IDENTITY

**ANDROGEL® logo DOs**



**The icon**

The green and blue commas in the logo are designed to resemble drops of gel.

**The colour**

Use brightly colored Cyan Blue and Anise Green to convey dynamism and how simple AndroGel® is to use.

**The font**

The font was designed especially for this product.

**ANDROGEL® logo DON'Ts**



Do not change the colors of the AndroGel® logo.



Do not change the typography of the AndroGel® logo.



Do not change the graphic style of the color touch of the AndroGel® logo.

**AndroGel®**  
16.2 mg/g gel  
(testosterone)

**Reverse logo**  
Total

**AndroGel®**  
16.2 mg/g gel  
(testosterone)

**Reverse logo**  
White & quadri

In some countries, Androgel® can be found under the brand name Testogel® or Androtop®.  
All are the same product, from the same manufacturer, the only difference is the brand name.

**Testogel®**  
1% gel  
(testosterone)

The logo graphic for Testogel consists of two thick, curved, overlapping shapes. The top shape is blue and the bottom shape is green, both curving upwards and to the right.

**Androtop®**

The logo graphic for Androtop consists of two thick, curved, overlapping shapes. The top shape is blue and the bottom shape is green, both curving upwards and to the right.

**16,2 mg/g, żel**  
*testosteronum*

## TESTOSTERONE BESINS logo DOs



### The icon

The Testosterone Besins icon showcases that Testosterone Besins is an intramuscular injectable.

### The colour

Orange is the accent color and demonstrates warmth, change and dynamic energy, while the gray typography softens the aggressiveness of the syringe.

### The font

For the name of the product, we use GILL SANS regular and for dosing and others informations we use Helvetica Neue LT pro light regular.

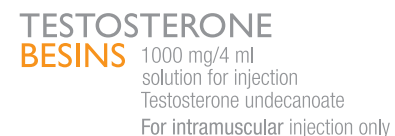
## TESTOSTERONE BESINS logo DON'Ts



Do not change the colours of the Testosterone Besins logo.



Do not change the typographie of the Testosterone Besins logo.



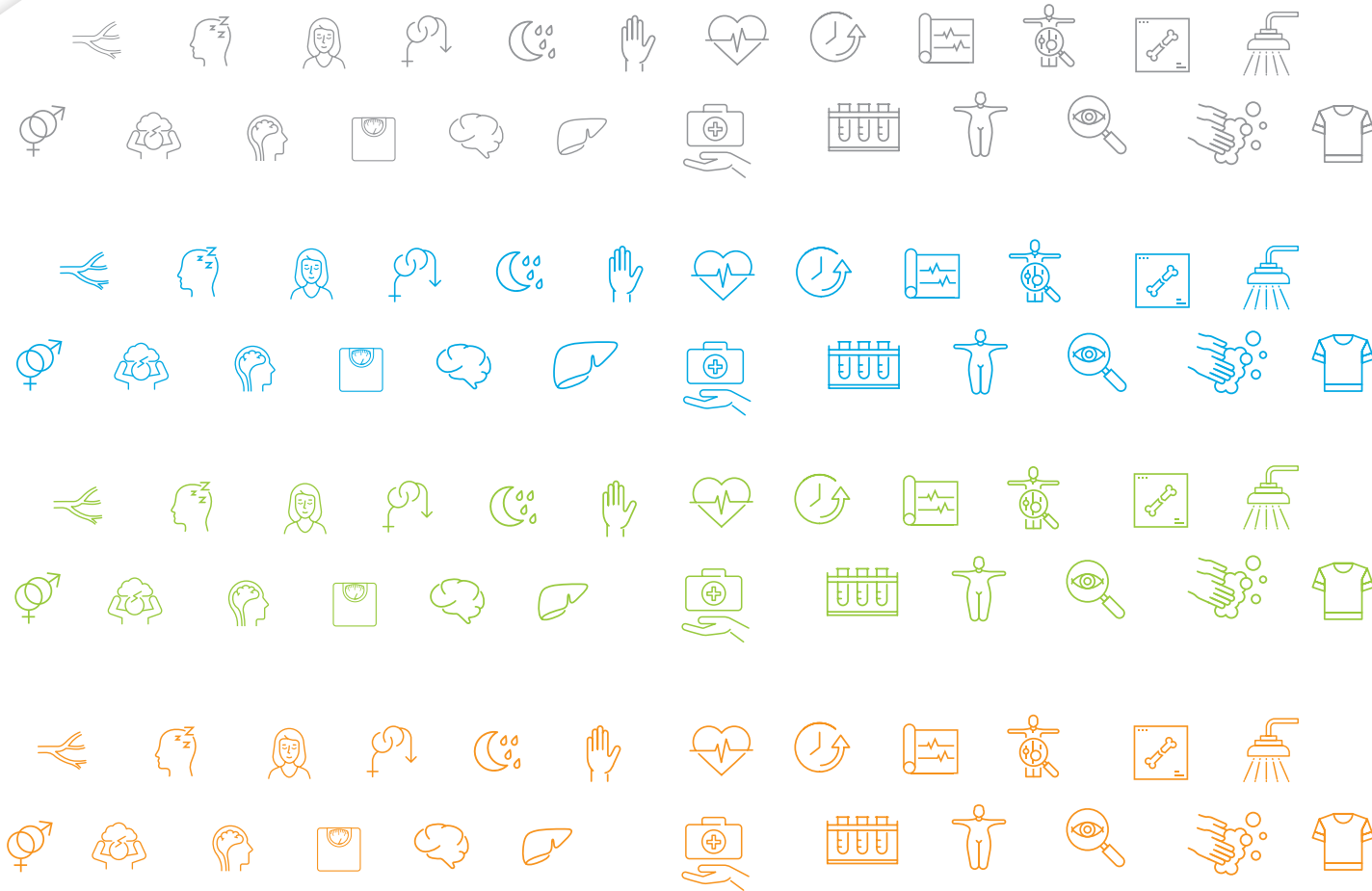
Do not use the Testosterone Besins logo without icon.



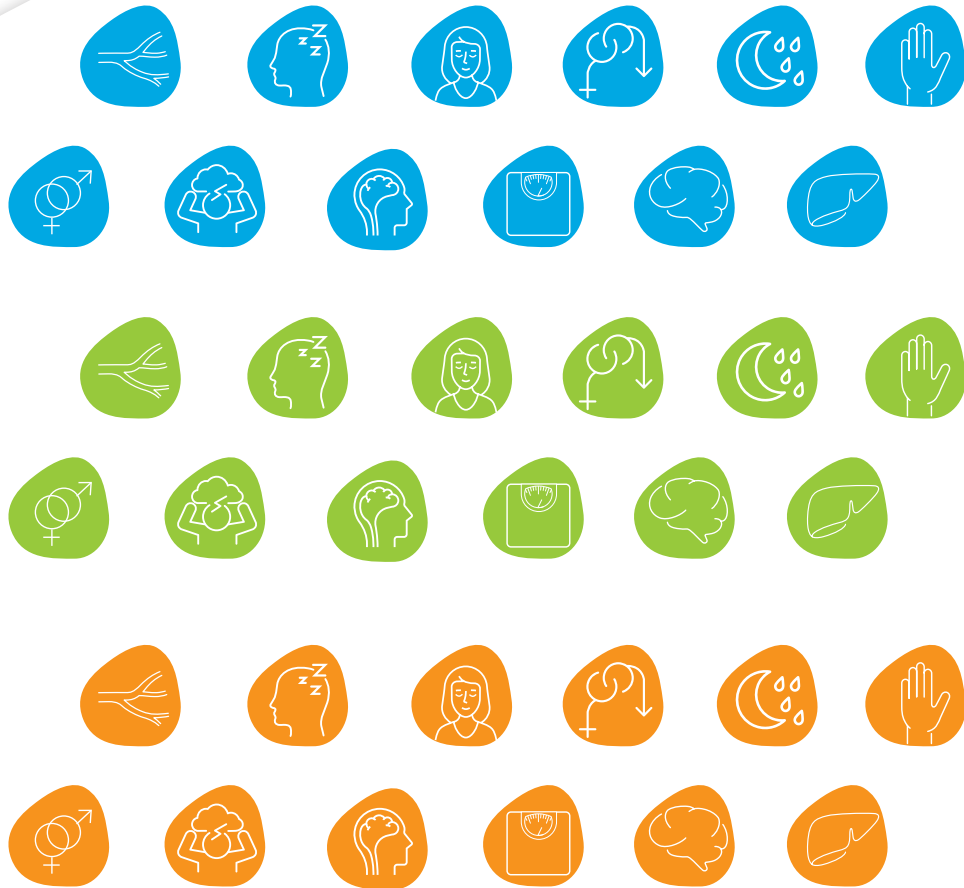
**Reverse logo**  
Total



**Reverse logo**  
White & quadri



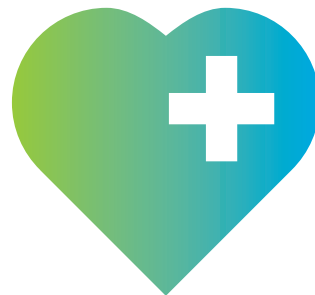
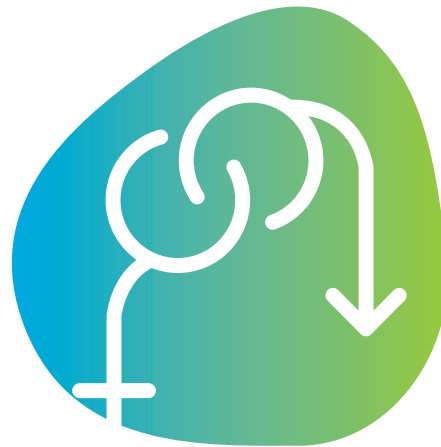
The recommended icons are stylized, sober and easy to understand. They represent symptoms, organs or characters (patients or HCPs). They can be used in any color shown on the chart (see page 48).



Icons can also be used with a pebble shape only in the colors shown on the chart (see page 48).



The pictograms can also be used on a gradient containing Androjel® colors.



## EDUCATED TEERS

ABCDEFGHIJKLMNOPQRSTUVWXYZ

0123456789

(Only to be used for the tagline)

Helvetica Neue LT pro  
47 condensed

abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789

Helvetica Neue LT pro  
57 condensed

abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789

Helvetica Neue LT pro  
77 condensed

**abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789**

Avenir Next  
regular

abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789

Avenir Next  
medium

abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789

Avenir Next  
bold

**abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789**

Avenir Heavy

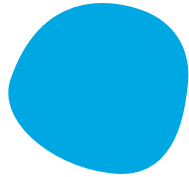
abcdefghijklmnopqrstuvwxy  
ABCDEFGHIJKLMNOPQRSTUVWXYZ  
0123456789

The colour environment refers to the combination of colours used to enhance product branding. These colours help to develop a consistent and distinctive visual identity in the product logo and within all communication pieces.



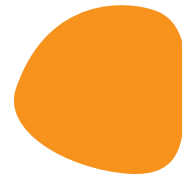
**TESTO/ANDROGEL  
LIME**

C46/M0/Y100/K0  
PMS 375C



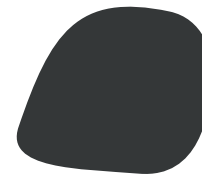
**TESTO/ANDROGEL  
SKY BLUE**

C80/M12/Y0/K0  
PMS 2198C



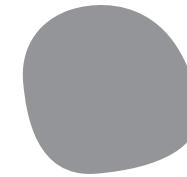
**TESTOSTERONE  
BESINS ORANGE**

C0/M50/Y100/K0  
PMS 151C



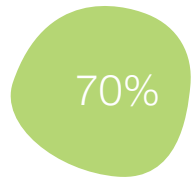
**ANTHRACITE**

C65/M55/Y55/K60  
PMS Black 7

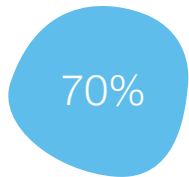


**PEARL GRAY**

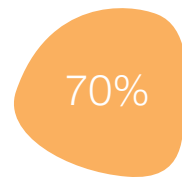
C0/M0/Y0/K50  
PMS 403C



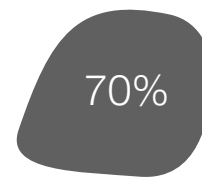
70%



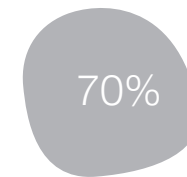
70%



70%



70%



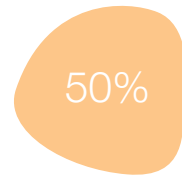
70%



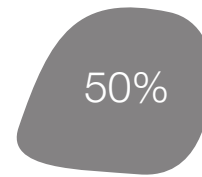
50%



50%



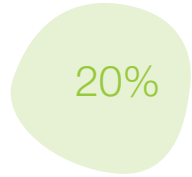
50%



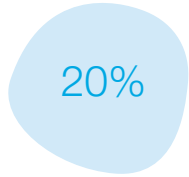
50%



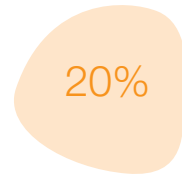
50%



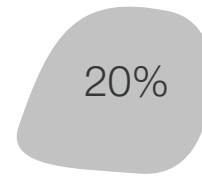
20%



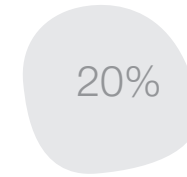
20%



20%



20%



20%

## Androgel®



## Testosterone Besins



## KEY VISUAL

Three key visuals have been created: **THE KISS**, **THE HUG**, and **THE SUPPORTERS**. **THE KISS** was the most liked visual by far in market research, but local affiliates can use any of these visuals which resonate with cultural sensitivities of their market.



THE KISS



THE HUG



THE SUPPORTERS

## KEY VISUAL CUSTOMIZATION BY PRODUCT TYPE

Matches product colors



Androgel® only  
Androgel®  
& Testosterone Besins

Matches product colors



Testosterone Besins only

## Key style of the overall brand

Please show men not bald and without a strong beard to match the hypogonadal profile

Before the TTh: pensive, with a serious and worried face expression about their health.



During and after TTh: smiling face, with confident and positive attitude. When we are talking about libido and sexual drive, we can use the couple imagery. However, the focus needs to be on the men and not women. Besides the images can't have a sexual connotation.



## LAYOUT print



Indication and symptom targets  
helvetica neue bold condensed -18 pt

Campaign tagline  
Educated tears -97 pt

Key visual

Products logos

Gel to show dosage form

Vial to show dosage form

Guidelines stamp  
bottom right

Besins logo  
bottom left

Baseline center  
helvetica neue bold condensed -17 pt



## LAYOUT digital

Indication and symptom targets

helvetica neue bold condensed



Campaign tagline

Educated tears

Key visual

Guidelines stamp

bottom right

Besins logo

Products logos

