Summary Report

# Testosterone Propionate

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
Grant number: 2U01FD005946

Prepared by:

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## REVIEW OF NOMINATIONS

Testosterone propionate (UNII code: WI93Z9138A) was nominated for inclusion on the 503B Bulks List by Fagron and Outsourcing Facilities Association (OFA). Testosterone propionate was nominated to treat constitutional growth delay, hypogonadism, low testosterone levels, and gender reassignment via a 50-100mg/mL intramuscular injection. Testosterone propionate will also be compounded in combination with testosterone cypionate. Doses range from 20mg in a combination product to 200mg as a single agent.

Reasons provided for nomination to the 503B Bulks List include:

- There are no FDA-approved products.
- Testosterone propionate is attached to a shorter ester and while it has a shorter retention time in the body, it contains more testosterone and is faster acting.
- Patients respond differently to drug products, so the compounded drug product may be the only product to effectively treat the indication for which it is intended to treat.
- It may be necessary to compound a product in a strength or dosage form that is not commercially available.
- Possible patient sensitivities to dyes, fillers, preservatives, or other excipients in the commercially available product.
- Manufacturer backorder

## METHODOLOGY

### *Background information*

The national medicine registers of 13 countries and regions were searched to establish the availability of testosterone propionate products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA) and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for testosterone propionate; name variations of testosterone propionate were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient(s); strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing testosterone propionate. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

*Systematic literature review*

Search strategy

Two databases (PubMed and Embase) were searched including any date through May 29, 2019. The search included a combination of ("testosterone propionate"[tiab]) AND (cypionate OR injection OR intramuscular) AND (humans[MeSH Terms] AND English[lang]) NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Literature reviews and/or meta-analyses, cost-effectiveness, and epidemiological studies were excluded. Testosterone propionate is a component of an FDA-approved product that has been discontinued by the manufacturer, not for safety or efficacy reasons. As a result, articles were excluded if testosterone propionate was utilized as the FDA-approved product or in the same concentration and formulation as the FDA-approved product. Articles were considered relevant based on the identification of a clinical use of testosterone propionate or the implementation of testosterone propionate in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

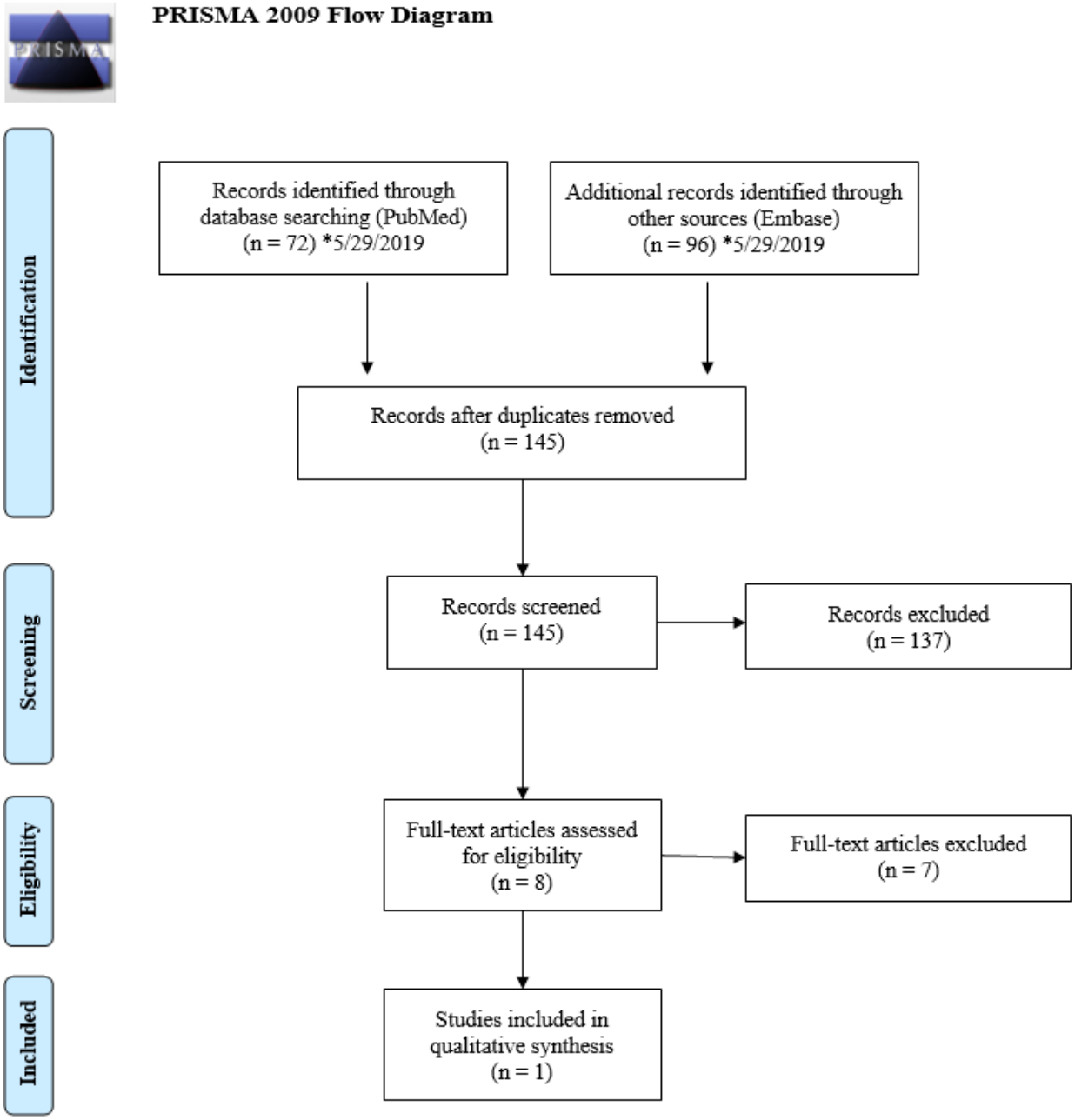
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for testosterone propionate use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of testosterone propionate compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)




*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

**For more information, visit www.prisma-statement.org.**

*Outreach to medical specialists and specialty organizations*

Using the indications from the nominations and the results of the literature review, seven (7) medical specialties that would potentially use testosterone propionate were identified: endocrinology, naturopathy, obstetrics and gynecology, oncology, pediatrics, primary care, and urology. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations or regulatory organizations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. Four (4) experts were contacted for interview, of which three (3) accepted and zero (0) declined interview. One (1) expert failed to respond to the interview request. Two (2) interviews were recorded and transcribed via ©Rev.com, while the other was not recorded due to equipment failure. QSR International's Nvivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

*Survey*

General professional medical associations and specialty associations for endocrinology, naturopathy, obstetrics and gynecology, oncology, pediatrics, primary care, and urology, identified from the nominations, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, leading professional organizations within that specialty, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to eleven (11) associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

| Specialty | Association |
|---|---|
| Naturopathy | American Association of Naturopathic Physicians (AANP) |
| Pediatrics | American Academy of Pediatrics (AAP) |
| Primary Care | American Academy of Environmental Medicine (AAEM) |

Table 2. Associations that declined participation

| Specialty | Association | Reasons for Declining |
|---|---|---|
| Endocrinology | American Association of Clinical Endocrinologists (AACE) | Declined, "Endocrinologists are not generally in the compounding space." |
| Medicine | American Medical Association (AMA) | Failed to respond |
| | American Osteopathic Association (AOA) | Failed to respond |
| Obstetrics and Gynecology | American College of Obstetricians and Gynecologists (ACOG) | Declined, survey not approved for distribution |
| Oncology | American Society of Clinical Oncology (ASCO) | Declined |
| Primary Care | American Academy of Family Physicians (AAFP) | Failed to respond |
| | American College of Physicians (ACP) | Failed to respond |
| Urology | American Urological Association (AUA) | Declined |

## CURRENT AND HISTORIC USE

*Summary of background information*

- Testosterone propionate is not available as an FDA-approved product (all previously approved products have been discontinued by the manufacturer not for safety or efficacy reasons).
- Testosterone propionate is not available as an OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for testosterone propionate.
- Testosterone propionate is available in Abu Dhabi, Australia, Belgium, Hong Kong, Latvia, New Zealand, Saudi Arabia, and the UK.

Table 3. Currently approved products – US

*No approved products in the US*

Table 4. Currently approved products – select non-US countries and regions[a]

| Active Ingredients | Concentration | Dosage Form | ROA | Approved For Use | | |
|---|---|---|---|---|---|---|
| | | | | Country | Status | Approval Date[b] |
| Testosterone decanoate<br>Testosterone isocaproate<br>Testosterone phenylpropionate<br>Testosterone propionate | – | Injectable | – | Hong Kong | Prescription only | 06/05/1979 |
| | 250mg/mL | Solution | | Abu Dhabi | Active | – |
| | | | – | Latvia | Prescription | 11/05/1997 |
| Testosterone decanoate 100mg<br>Testosterone isocaproate 60mg<br>Testosterone phenylpropionate 60mg<br>Testosterone propionate 30mg | 250mg/mL | Solution | – | New Zealand | Prescription | 12/31/1969 |
| | | Injection | Intramuscular | Saudi Arabia | Prescription | – |
| | | Solution | | Australia | Schedule 4- Prescription only | 09/20/1991 |
| | | | | Belgium | Medical prescription | 03/01/1962 |
| | | | | UK | Prescription-only | 02/28/1973 |
| Testosterone isocaproate 40mg<br>Testosterone phenylpropionate 40mg<br>Testosterone propionate 20mg | 100mg/mL | Injection | Intramuscular | Saudi Arabia | Prescription | – |

Abbreviations: "–", not mentioned; ROA, route of administration

[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, route of administration and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or routes of administration similar to those requested in the nominations. See Methodology for full explanation.

[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

*Summary of literature review*

Only one (1) article was identified that met the inclusion criteria.

Table 5. Types of studies

| Types of Studies | Number of Studies |
|---|---|
| Observational[1] | 1 |

Table 6. Number of studies by country

| Country | Number of Studies |
|---|---|
| Italy[1] | 1 |
| | Total US: 0<br>Total non-US Countries: 1 |

Table 7. Number of studies by combinations

| | Combination Formula | Number of Studies |
|---|---|---|
| **Nominated** | Testosterone propionate 20mg / Not mentioned – intramuscular injection | 0 |

Table 8. Dosage by indication – US

*No US studies included*

Table 9. Dosage by indication – non-US countries

| Indication | Dose | Concentration | Dosage Form | ROA | Duration of Treatment |
|---|---|---|---|---|---|
| Breast cancer[1] | 250mg | – | – | Intramuscular | 8 weeks |

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 10. Compounded products – US

*No US studies included*

Table 11. Compounded products – non-US countries

*No compounded products from reported studies*

*Summary of focus groups/interviews of medical experts and specialty organizations*

Three (3) interviews were conducted. For one interview, the audio recording did not function and therefore no transcript is available. One (1) medical expert with a Doctor of Medicine (MD) specializing in oncology failed to respond to the interview request.

Table 12. Overview of interviewees

| Interviewee | Level of Training | Specialty | Current Practice Setting | Experience with Testosterone Propionate | Interview Summary Response |
|---|---|---|---|---|---|
| OBG_01 | MD | Obstetrics and Gynecology | Large midlife health center | Does not use testosterones frequently, avoids using compounded testosterone products | • Interviewee has concerns about compounded hormone therapy.<br>• No reason to stock in office.<br>• Does not see the need to use in combination with testosterone cypionate.<br>• Interviewee mostly discussed the use of testosterone pellets, not the intramuscular injection. |
| END_01 | MD | Internal Medicine<br>Endocrinology and Metabolism | Academic medical institution | Not specified | • 98% of times, interviewee would use FDA-approved testosterone products.<br>• There is no need to administer in office. |
| END_03 | MD | Endocrinology | Academic medical institution | No | • Does not use testosterone propionate, usually uses cypionate.<br>• Does not see strong medical need for propionate. |

Abbreviation: MD, Doctor of Medicine.

Concerns with compounded hormone therapy

- One (1) interviewee stated, "we held a phone call last October with the FDA as a group of societies **REDACTION** and met with multiple people from the FDA to raise some concerns about compounding hormone therapy, about the prevalence, about our concern about the limited group of people that should be receiving non-approved compounded hormone products. And our concerns about patient safety due to the lack of adequate regulatory oversight, lack of package inserts, and standard warnings. And then the false and misleading claims about bioidentical hormones."
- One (1) interviewee stated, "there's a lot of concern that we are giving post-menopausal women very high levels of hormones without any data showing safety or efficacy or need for those high doses."

Office stock:

- All interviewees stated there is no need to stock compounded testosterone propionate in office.
- One (1) interviewee stated, "I wouldn't use it very much" and "I wouldn't trust that it stay stable."
- One (1) interviewee stated, "there's more potential for abuse by having it in people's office."

Supplemental information:

- One (1) interviewee provided references regarding the serious health and safety risks associated with the use of compounded "bioidentical" hormone products in menopausal women, as well as scientific, positional statements, and other publicly available documents nominating hormones to the demonstrably difficult to compound list.[2-12]
    - The references provided information regarding testosterone. However, there was no specific information regarding testosterone propionate for intramuscular use.

*Summary of survey results*

Table 13. Characteristics of survey respondents [70 people responded to the survey[a]]

| Board Certification | MD | ND | No Response | PharmD |
|---|---|---|---|---|
| Anesthesiology | 7 | 0 | 0 | 0 |
| Clinical pharmacology | 1 | 0 | 0 | 0 |
| Critical care medicine | 3 | 0 | 0 | 0 |
| Endocrinology, diabetes, and metabolism | 0 | 1 | 0 | 0 |
| Fellow of the American Board of Naturopathic Oncology | 0 | 1 | 0 | 0 |
| Gastroenterology | 1 | 0 | 0 | 0 |
| Hospice and palliative medicine | 1 | 0 | 0 | 0 |
| Naturopathic Doctor | 0 | 6 | 0 | 0 |
| Naturopathic Physician | 0 | 9 | 0 | 0 |
| Pediatrics | 5 | 0 | 0 | 0 |
| Pediatrics anesthesiology | 3 | 0 | 0 | 0 |
| No Board certification | 1 | 4 | 0 | 1 |
| No response | 0 | 0 | 44 | 0 |

Abbreviations: MD, Doctor of Medicine; ND, Naturopathic Doctor; PharmD, Doctor of Pharmacy.

[a]Some respondents reported more than one terminal clinical degree or one board certification.

Table 14. Types of products used, prescribed, or recommended

| Types of Products | Respondents, n (N=14[a]) |
|---|---|
| Compounded | 1[b] |
| FDA-approved | 2 |
| Over-the-counter | 0 |
| Dietary | 0 |
| Unsure | 0 |
| No response | 11 |

[a]Out of 70 respondents, 14 reported using, prescribing, or recommending multiple types of testosterone propionate product.
[b]One respondent used in combination: testosterone propionate 20mg/mL / testosterone cypionate 200mg/mL.

Table 15. Compounded use of testosterone propionate in practice

*No survey respondents provided this information*

Table 16. Indications for which testosterone propionate is considered a standard therapy

| Indication | Standard Therapy | |
|---|---|---|
| | Compounded, n (N=1) | Non-compounded, n (N=13) |
| Andropause, transgenderism | 0 | 1 |
| Hormone supplementation or suppression | 0 | 1 |
| No response | 0 | 11 |
| Not that many | 1 | 0 |

Table 17. Reasons for using a compounded product instead of any FDA-approved product

| Reasons |
|---|
| • "Better" |

Table 18. Change in frequency of compounded testosterone propionate usage over the past 5 years

| | **Respondents, n (N=1)** |
|---|---|
| No - use has remained consistent | 0 |
| Yes - I use it LESS often now[a] | 1 |
| Yes - I use it MORE often now | 0 |

[a]One respondent wrote "not needed".

Table 19. Do you stock non-patient specific compounded testosterone propionate in your practice?

| | **Respondents, n (N=1)** |
|---|---|
| No | 1 |
| Yes | 0 |

Table 20. Questions related to stocking non-patient specific compounded testosterone propionate

*No survey respondents provided this information*

## CONCLUSION

Testosterone propionate (UNII code: WI93Z9138A) was nominated for inclusion on the 503B Bulks List by Fagron and OFA for constitutional growth delay, hypogonadism, low testosterone levels, and gender reassignment. The nominated route of administration and dosage form is an intramuscular injection. Testosterone propionate is approved in eight (8) of the 11 foreign medicine registries searched.

From the literature review conducted, no US studies were found. The most common indication for use from the non-US studies was breast cancer. No compounded products were identified from any studies.

From the interviews, both interviewees preferred FDA-approved testosterone propionate products to compounded testosterone propionate products, and both said there is no need to stock compounded products in office. One interviewee expressed concerns about compounded hormone therapy.

From the survey responses, 14 out of 70 respondents used testosterone propionate. Out of 14, one (1) respondent used compounded testosterone propionate, but did not give details on how it was used. The reasons provided for using a compounded testosterone propionate product over an FDA-approved product was better quality. No respondents reported stocking compounded testosterone propionate in their office.

## APPENDICES

*Appendix 1. References*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*Appendix 2. Survey instrument*

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**Start of Block: Welcome Page**

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **testosterone propionate**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

**End of Block: Welcome Page**

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**Start of Block: Testosterone propionate**

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **testosterone propionate**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

*Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for testosterone propionate? Pleas... != Compounded drug product*

*Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for testosterone propionate? Pleas... = Compounded drug product*

*Display This Question:*

*If What type(s) of product(s) do you use, prescribe, or recommend for testosterone propionate? Pleas... = Compounded drug product*

Q2. Please list any conditions or diseases for which you use compounded **testosterone propionate** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

| | Strength(s) (please include units) | Dosing frequency(ies) | Dosage form(s) | Route(s) of administration | Duration of therapy | Patient population |
|---|---|---|---|---|---|---|
| Condition 1 (please describe) | | | | | | |
| Condition 2 (please describe) | | | | | | |
| Condition 3 (please describe) | | | | | | |
| Condition 4 (please describe) | | | | | | |
| Condition 5 (please describe) | | | | | | |

Q3. Do you use compounded **testosterone propionate** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

*Skip To: Q5 If Do you use compounded testosterone propionate as a single agent active ingredient, or as one acti... != Combination*

*Display This Question:*

*If Loop current: Do you use compounded testosterone propionate as a single agent active ingredient, or as one acti... = Combination*

Q4. In which combination(s) do you use compounded **testosterone propionate**? Please check all that apply.

- ☐ Testosterone propionate 20mg/mL / Testosterone cypionate 200mg/mL
- ☐ Other (please describe) _____

Q5. For which, if any, diseases or conditions do you consider compounded **testosterone propionate** standard therapy?

_____

Q6. Does your specialty describe the use of compounded **testosterone propionate** in medical practice guidelines or other resources?

_____

Q7. Over the past 5 years, has the frequency in which you have used compounded **testosterone propionate** changed?

- ○ Yes - I use it **MORE** often now (briefly describe why) _____
- ○ Yes - I use it **LESS** often now (briefly describe why) _____
- ○ No - use has remained consistent

Q8. Why do you use compounded **testosterone propionate** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **testosterone propionate** in your practice location?

- ○ Yes
- ○ No

*Skip To: End of Block If Do you stock non-patient-specific compounded testosterone propionate in your practice location? = No*

*Display This Question:*

*If Do you stock non-patient-specific compounded testosterone propionate in your practice location? = Yes*

Q10. In what practice location(s) do you stock non-patient-specific compounded **testosterone propionate**? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **testosterone propionate**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **testosterone propionate**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe) _____

*Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone propionate? Please check... = Convenience*

*Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone propionate? Please check... = Emergencies*

*Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone propionate? Please check... = Other (please describe)*

Q13. For which, if any, diseases or conditions do you consider **testosterone propionate** standard therapy?

_____

Q14. Does your specialty describe the use of **testosterone propionate** in medical practice guidelines or other resources?

_____

**End of Block: Testosterone propionate**

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**Start of Block: Background Information**

Q15. What is your terminal clinical degree? Please check all that apply.

- ☐ Doctor of Medicine (MD)
- ☐ Doctor of Osteopathic Medicine (DO)
- ☐ Doctor of Medicine in Dentistry (DMD/DDS)
- ☐ Naturopathic Doctor (ND)
- ☐ Nurse Practitioner (NP)
- ☐ Physician Assistant (PA)
- ☐ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ☐ No Board certification
- ☐ Allergy and Immunology
- ☐ Anesthesiology
- ☐ Cardiovascular Disease
- ☐ Critical Care Medicine
- ☐ Dermatology
- ☐ Emergency Medicine
- ☐ Endocrinology, Diabetes and Metabolism
- ☐ Family Medicine
- ☐ Gastroenterology
- ☐ Hematology
- ☐ Infectious Disease
- ☐ Internal Medicine

- [ ] Medical Toxicology
- [ ] Naturopathic Doctor
- [ ] Naturopathic Physician
- [ ] Nephrology
- [ ] Neurology
- [ ] Obstetrics and Gynecology
- [ ] Oncology
- [ ] Ophthalmology
- [ ] Otolaryngology
- [ ] Pain Medicine
- [ ] Pediatrics
- [ ] Psychiatry
- [ ] Rheumatology
- [ ] Sleep Medicine
- [ ] Surgery (please describe) _____
- [ ] Urology
- [ ] Other (please describe) _____

**End of Block: Background Information**