

Hormone Therapy in Gender Dysphoria

AMBERO

Prescribing for **trans men** (this applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male)

Prescribing Information Sheet: To be read in conjunction with the relevant SPCs

NHS England (NHSE) commission specialist gender identity centres. NHSE have stated that the patient's GP is responsible for organising blood and other diagnostic tests and for prescribing pharmacological treatments as recommended by the specialist identity centres. Therefore, it is likely that GPs will be requested to prescribe hormones for patients that are under the care of a specialist identity centre.

However, **NHSE has also stated that GICs should retain responsibility for providing prescriptions and for monitoring until the GP has agreed to a transfer of responsibilities. Individual prescribers MUST only prescribe within their own level of competence.**

The General Medical Council (GMC) have put together a set of ethical guidance on trans healthcare which can be accessed via: <https://www.gmc-uk.org/ethical-guidance/ethical-hub/trans-healthcare>. A summary of the main points follows:

- GPs can prescribe unlicensed medicines following the steps set out in GMC guidance
- If a patient is self-medicating with hormones that have been purchased, consider issuing a bridging prescription as part of a harm reduction approach. Seek the advice of an experienced gender specialist.

The following tables contain information relating to the most commonly requested hormone replacement therapies. **This information relates to trans men (a person assigned female, cis-female, at birth undertaking gender transition to become a male) only.** There is a separate prescribing sheet available for trans women (a person assigned male, cis-male, at birth undertaking gender transition to become a female) available on the LMMG website via www.lancsmmg.nhs.uk.

Table 1. Preparations for trans men (this applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male)		
Medication	Typical Dosing and Product Information off label use	Additional Information (See table 3 and 4 for Side Effects and Interactions)
Testosterone PC	Testogel® 50mg/5g sachets – Apply 50 to 100mg daily Tostran® 10mg/0.5ml pump – Apply 30 to 80mg daily	Apply to clean dry skin Apply to clean dry skin; one pump application = 10mg testosterone. CD Sch. 4. Life-long therapy.
Testosterone decanoate, isocaproate, phenylpropionate and propionate IM	Sustanon® 250 – 1ml every TWO to SIX weeks	Can be considered for self-administration. Contains peanut oil. CD Sch. 4. Life-long therapy.
Testosterone enantate IM	Generic – 1ml every TWO to SIX weeks	Can be considered for self-administration. CD Sch. 4. Life-long therapy.
Testosterone undecanoate IM	Nebido® 1g/4ml – 250 to 1000mg every 10 – 20weeks	Not suitable for self-administration. Steady-state reached after third dose – take blood for trough level just before administration of fourth dose. CD Sch. 4. Life-long therapy.
Leuprorelin acetate SC or IM	Prostap® SR DCS or Prostap® 3 DCS – 3.75 to 11.25mg every ONE, TWO or THREE months (as advised by the specialist centre).	Can be considered for self-administration. Typically used for refractory uterine bleeding.
Triptorelin IM	Decapeptyl SR 11.25mg Salvacyl 11.25mg	Not suitable for self-administration. Typically used for refractory uterine bleeding.
Triptorelin acetate SC or IM	Decapeptyl SR 3mg Gonapeptyl Depot 3.75mg 3 to 11.25mg every ONE, TWO or THREE months (as advised by the specialist centre)	
Table 2. Dose adjustment of testosterone therapy. Seek further advice from the patient's original gender identity clinic if unable to achieve level in the therapeutic range.		
<p>Dose titration of testosterone gel preparations: Testogel®: if the testosterone level (taken 4 – 6 hours after application) >20nmol/L reduce dose by (25mg) ½ a sachet daily. If the testosterone level is <15nmol/L increase dose by 50mg (ONE sachet) daily. In both cases recheck levels in EIGHT weeks. Tosteran®: if the testosterone level (taken 4 – 6 hours after application) >20nmol/L reduce dose by 10mg (ONE pump) daily. If the testosterone level is <15nmol/L increase dose by 10mg (ONE pump) daily. In both cases recheck levels in EIGHT weeks.</p>		

Dose titration of testosterone injectable preparations: if the trough testosterone level (taken immediately before the last dose) is >12nmol/L decrease the frequency of injections e.g. if receiving every THREE weeks reduce to every FOUR weeks. If the trough testosterone level is <8nmol/L increase the frequency of injection (e.g. if receiving every THREE weeks increase to every TWO weeks. In both cases recheck levels in THREE months.

Table 3. Monitoring and review requirements

The following tests or measurements should be monitored in primary care every SIX months for THREE years after starting hormone therapy and continued ONCE yearly thereafter.

Test or Measurement	Recommended action if the result is outside of the normal range
Body Mass Index	Manage according to local guidelines if BMI increases to over 30 – only necessary in this context if the patient is considering surgery.
Blood pressure	Manage according to local guidelines if BP greater than 140/90mmHg.
Haemoglobin and haematocrit	If a patient becomes significantly polycythaemic (haemoglobin > 175g/L or haematocrit >0.52 or 52%) or experiences a thrombotic event, testosterone treatment should be temporarily suspended and a haematology referral made – seek further advice from the patient's original gender identity clinic.
Urea and electrolytes	If out-of-range, seek further advice from the patient's original gender identity clinic.
Liver function tests	If elevated, refer to gastroenterology – seek further advice from the patient's original gender identity clinic.
HbA1c	If elevated, manage according to local guidelines.
Lipid profile	If elevated, manage according to local guidelines.
Serum testosterone	Serum testosterone should be at the lower end of the normal range. Measure trough level for injectables (trough range < 8 – 12 nmol/L; peak range 25 – 30nmol/L). Take sample to measure levels for gel preparations 4 – 6 hours after application (target is 17 – 18nmol/L; range 15 – 20nmol/L).
Serum estradiol	Target range < 70pmol/L; Seek advice from the patient's original gender identity clinic.
Serum prolactin	Target range < 400mU/L; Seek advice from the patient's original gender identity clinic.

Table 4. Summary of medication side effects Please refer to the individual medications [SPC](#) for more details

<p>Testosterone</p> <p>Likely increased risk</p> <p>Polycythaemia*(see below for further details) Weight gain Acne Androgenic alopecia (balding) Sleep apnoea</p> <p>Possible increased risk</p> <p>Altered lipid profiles ** Liver dysfunction</p> <p>Possible increased risk with presence of additional risk factors</p> <p>Type 2 diabetes** Hypertension** Mania and psychosis in patients with pre-existing disorders* Cardiovascular disease</p> <p>No increased risk or inconclusive</p> <p>Breast Cancer, Osteoporosis, Cervical cancer, Ovarian cancer, Uterine cancer</p> <p>*Risk is greater with supraphysiologic (beyond normal male range) serum levels of testosterone, which are more likely to be found with extended intramuscular dosing, than transdermal administration</p> <p>**Patients with Polycystic Ovarian Syndrome may be at greater risk</p>	<p>Leuprorelin</p> <p>Common or very common</p> <p>Appetite decreased; arthralgia; bone pain; breast abnormalities; depression; dizziness; fatigue; gynaecomastia; headache; hepatic disorders; hot flush; hyperhidrosis; injection site necrosis; insomnia; mood altered; muscle weakness; nausea; paraesthesia; peripheral oedema; sexual dysfunction; testicular atrophy; vulvovaginal dryness; weight change</p> <p>Uncommon</p> <p>Alopecia; diarrhoea; fever; myalgia; palpitations; visual impairment; vomiting</p> <p>Rare or very rare</p> <p>Haemorrhage</p> <p>Frequency not known</p> <p>Anaemia; glucose tolerance impaired; hypertension; hypotension; leucopenia; paralysis; pulmonary embolism; QT interval prolongation; seizure; spinal fracture; thrombocytopenia; urinary tract obstruction</p> <p>Triptorelin</p> <p>Common or very common</p>
<p>Table 5. Interactions Please refer to the individual medications SPC for more details</p>	

<p>Testosterone</p> <p>Testosterone can enhance the blood glucose-lowering effects of insulin.</p> <p>Increased anticoagulant effects and bleeding have been seen in patients taking a coumarin and an anabolic steroid or testosterone.</p> <p>Leuprorelin and Triptorelin</p> <p>The concomitant use of leuprorelin or triptorelin with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated.</p> <p>Triptorelin</p> <p>Drugs which raise prolactin levels should not be prescribed concomitantly as they reduce the level of GnRH receptors in the pituitary.</p> <p>When triptorelin is co-administered with drugs affecting pituitary secretion of gonadotropins, caution should be exercised and it is recommended that the patient's hormonal status be supervised.</p>	<p>Asthenia; depression; dizziness; dysuria; gastrointestinal discomfort; gynaecomastia; haemorrhage; headache; hot flush; hyperhidrosis; hypersensitivity; joint disorders; menstrual cycle irregularities; mood altered; muscle complaints; nausea; oedema; ovarian and fallopian tube disorders; pain; painful sexual intercourse; paraesthesia; pelvic pain; sexual dysfunction; sleep disorders; vulvovaginal dryness</p> <p>Uncommon</p> <p>Alopecia; appetite abnormal; asthma exacerbated; breast pain; chills; constipation; diarrhoea; drowsiness; dry mouth; dyspnoea; embolism; gout; hypertension; muscle weakness; skin reactions; testicular disorders; tinnitus; vision disorders; vomiting; weight changes</p> <p>Rare or very rare</p> <p>Abnormal sensation in eye; chest pain; confusion; diabetes mellitus; difficulty standing; fever; flatulence; hypotension; influenza like illness; memory loss; musculoskeletal stiffness; nasopharyngitis; orthopnoea; osteoarthritis; taste altered; vertigo</p> <p>Frequency not known</p> <p>Angioedema; anxiety; bone disorder; malaise; QT interval prolongation</p>
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Bibliography

- Besins Healthcare (UK) Ltd. Testogel - Summary of Product Characteristics (SmPC) - (eMC) 2019 [Available from: <https://www.medicines.org.uk/emc/product/6808/smpc#>]
- General Medical Council (GMC). Trans healthcare 2019 [Available from: <https://www.gmc-uk.org/ethical-guidance/ethical-hub/trans-healthcare>].
- Ipsen Ltd. Decapeptyl SR 3mg - Summary of Product Characteristics (SmPC) - (eMC) of first authorisation: 29 December 1994 Date of last renewal: 13 September 2001 [Available from: <https://www.medicines.org.uk/emc/product/963/smpc#INTERACTIONS>].
- Preston CL, Stockley IH. Stockley's drug interactions : a source book of interactions, their mechanisms, clinical importance and management 2019.
- Royal Pharmaceutical Society. BNF: British National Formulary - NICE. 2019.
- Sheffield Gender Identity Clinic. Prescribing Guidelines: Trans man medication (This applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male). Version 11. Sheffield Health and Social Care NHS Foundation Trust. 2017.
- The World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People: The World Professional Association for Transgender Health; 2012. 112 p.
- Takeda UK Ltd. Prostap 3 DCS - Summary of Product Characteristics (SmPC) - (eMC) of first authorisation: 28/04/2011 Date of Renewal: 26/04/2016 [Available from: <https://www.medicines.org.uk/emc/product/4651/smpc#>].

Please access this guidance via the LMMG website to ensure that the correct version is in use.

Version Control

Version Number	Date	Amendments Made
Version 1.0	July 2019	New guideline. AG.
Version 1.1	March 2021	Prescribing responsibility updated. AG.

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