

Besins Healthcare reassures on testosterone supply

Ample supplies of Testogel pump, which is unaffected by shortages of sachets

The manufacturer of testosterone replacement therapy Testogel (1% transdermal testosterone gel) says patients must visit their prescribing doctor in order to switch to the metered dose pump presentation as soon as possible to avoid their treatment being impacted by supply issues with the sachet presentation.

Besins Healthcare today confirmed that global supply had been interrupted and that Testogel sachets will be unavailable in Australia for several months. In order to avoid treatment disruption, patients treated with Testogel sachets will need to secure a new prescription for the Testogel pump presentation – which is unaffected by supply issues and remains the preferred option.

Testogel sachets and Testogel pump provide the same strength and dose range, but because testosterone replacement therapy prescriptions must specify both a brand and a presentation, a new prescription is required to switch between them. Patients may obtain this new prescription from their GP without revisiting a specialist. GPs will need to ring the PBS approvals line and quote the name of the original specialist to obtain a new Authority Required approval.

“Supply challenges mean Testogel sachets will become unavailable for a period of time, but there are no issues with supply of the pump. Patients with scripts for Testogel sachets must see their prescribing doctor without delay in order to switch to the pump presentation and ensure continuity of treatment,” said Geoff Blundell, Managing Director of Besins Healthcare.

Mr Blundell apologised for any inconvenience arising from the supply issue, especially as it follows the unexpected withdrawal of competitor product, Axiron (2% w/v transdermal testosterone solution) at the end of last year, which has created increased demand for Testogel.

“We extend our sincerest apologies to patients, doctors and pharmacists for any disruption, especially coming at a time when there is already uncertainty in the market. We hope that our previous communications stating the pump presentation is the preferred option for patients switching from Axiron, in anticipation of supply challenges with the sachet, have been of some help,” Mr Blundell added.

Besins would like to clarify that:

- Testogel is NOT being discontinued.
- Sachet presentations are currently subject to stock shortages and this presentation will be unavailable in Australia for several months. Testogel sachets are not being discontinued.
- There is no stock supply pressure on the pump presentation of Testogel. The metered-dose pump pack provides the same strength and dose range as Testogel sachets.
- GPs can write a new prescription for the pump presentation without sending the patient back to the specialist. They will need to phone the PBS approvals line and quote the name of the original specialist to obtain a new Authority Required approval.

“We would like to thank everyone for their understanding and loyalty and hope to minimise any inconvenience during this period of adjustment. We will continue to support doctors, patients and pharmacists during the switch across to the pump presentation,” Mr Blundell concluded.

For a clinical perspective on testosterone replacement therapy, please contact the following specialists:

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PBS Information

Authority required. Refer to PBS Schedule for full information.

Minimum Product Information:

Testogel® (Minimum Product Information) Testogel is 1% testosterone gel. INDICATIONS: Testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests. **CONTRAINDICATIONS:** known or suspected prostatic cancer/breast carcinoma; known hypersensitivity to testosterone or any other ingredient, use in women or children. **PRECAUTIONS:** Regular monitoring of the prostate gland and breast, hypercalcaemia, severe cardiac, hepatic or renal insufficiency, ischaemic heart disease, hypertension, diabetes, epilepsy and migraine. Risk of sleep apnoea. Effect on doping tests. Must not be used in women. Testosterone transfer to others via skin contact. Must not be used in pregnant women. Must not be used in breast-feeding women. **INTERACTIONS WITH OTHER MEDICINES:** Oral anticoagulants, ACTH or corticosteroids, oxyphenbutazone, insulin requirements, bupropion, cyclosporine. In general, any substance which affects liver function should not be taken with testosterone. **ADVERSE EFFECTS:** Reaction at the application site, erythema, acne, dry skin, changes in laboratory tests, headache, prostatic disorders, gynaecomastia, mastodynia, dizziness, paraesthesia, amnesia, hyperaesthesia, mood disorders, hypertension, diarrhoea, alopecia, urticaria. **DOSAGE AND ADMINISTRATION: Adult Men:** 5g of gel applied once daily at about the same time, preferably in the morning. Depending on clinical/laboratory response, the dose may be adjusted by 2.5g steps to a maximum 10g of gel per day.