

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Testogel 50mg Gel in Sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet of 5 g contains 50 mg of testosterone.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from the UK and Greece:
Gel in Sachet
Transparent or slightly opalescent, colourless gel in a sachet.

4 CLINICAL PARTICULARS

As per PA1054/002/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA1054/002/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 980
Isopropyl myristate
Ethanol 96%
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

5 g in sachet (PET/Aluminium/LDPE).
Box 30 sachets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/306/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th April 2013

10 DATE OF REVISION OF THE TEXT