

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Testogel 50 mg transdermal gel in sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet of 5 g contains 50 mg of testosterone.

Excipient(s) with known effect: Ethanol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal gel.

Product imported from Norway

Transparent or slightly opalescent, colourless gel in 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 for 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 of 30 sachets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4/C3,
Metropoint Business Park,
Kettles Lane,
Swords,
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st May 2024

10 DATE OF REVISION OF THE TEXT