

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Divigel 0.1% w/w Gel, 1 mg/dose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Estradiol hemihydrate corresponding to 1.0 mg estradiol per single dose container.

Excipients with known effect

Contains propylene glycol and ethanol (96%).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel, single-dose container

Product imported from France

Smooth, opalescent gel

4 CLINICAL PARTICULARS

As per PA1327/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1327/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 974 P

Trolamine

Propylene glycol (E1520)

Ethanol (96 per cent)

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 as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25

6.5 Nature and contents of container

Single dose aluminium foil sachets packed in cardboard outer cartons containing 28 x 1.0 g

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

PPA23080/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 21st April 2023

10 DATE OF REVISION OF THE TEXT