Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Evorel Conti 50/170 micrograms per 24 hours transdermal patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each transdermal patch contains 3.2 mg estradiol hemihydrate equivalent to 3.1 mg estradiol and 11.2 mg norethisterone acetate, in a patch size of 16 cm^2, releasing a nominal 50 microgram estradiol and 170 microgram norethisterone acetate per 24 hours.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Transdermal patch

Product imported from Poland
Each patch has an area of 16 cm^2. Patches are square with rounded corners. A patch is made of a flat, two-layer laminate. The outer layer is a nearly colourless backing film. It is marked on the outer side with 'CEN1' in the centre of the lower edge. The inner layer is an adhesive film. The adhesive layer is protected by a clear release liner, which is removed prior to application. The release liner has a S-shaped incision to facilitate its removal prior to use.

4 CLINICAL PARTICULARS

As per PA22668/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22668/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Adhesive:
Acrylic copolymer
Guar gum
Backing film:
Polyester
Release liner:
Polyethylene terephthalate

6.2 Incompatibilities

No creams, lotions, or powders should be applied to the skin area where the patch is to be applied to prevent interference with the adhesive properties of the patch.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the sachet and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C. Keep in the original sachet and carton.

6.5 Nature and contents of container

Each carton has 8 transdermal patches in individual sachets.

6.6 Special precautions for disposal and other handling

Patches should be placed on a clean, dry area of skin on the trunk of the body below the waist. Creams, lotions, shower soaps, oils, liniments or powders may interfere with the adhesive properties of the patch. The patch should not be applied on or near the breasts. The area of application should be changed, with an interval of at least one week allowed between applications to a particular site. The skin area selected should not be damaged or irritated. The waistline should not be used because excessive rubbing of the patch may occur.

Patches should be used immediately after opening the sachet. Remove one part of the protecting foil. Apply the exposed part of adhesive to the application site from the edge to the middle; avoid wrinkling of the patch. The second part of the protective foil should now be removed and the freshly exposed adhesive applied. Wrinkling should again be avoided. The palm of the hand should be used to press the patch onto the skin for approximately 30 seconds and to bring the patch to skin temperature at which the adhesive effect is optimised. Do not touch the adhesive part of the patch.

To remove the patch, peel away an edge of the patch and pull smoothly away from the skin.

Any gum that remains on the skin after removal of the patch may be removed by rubbing it off with the fingers or washing with soap and water or by using baby oil.

Patches should be folded in half and disposed of in household waste (do not flush down the toilet).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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Ashbourne,
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/489/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2022

10 DATE OF REVISION OF THE TEXT