Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Femoston-conti 1 mg/5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains estradiol hemihydrate equivalent to 1 mg estradiol and 5 mg dydrogesterone.
Excipient with known effect: lactose monohydrate
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Bulgaria
Round, biconvex marked 379 on one side. Salmon coloured tablets.

4 CLINICAL PARTICULARS

As per PA2010/012/004

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/012/004

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Hypromellose
Maize starch
Colloidal anhydrous silica
Magnesium stearate

Film coat:
Hypromellose
Macrogol 400
Titanium dioxide (E171)
Iron oxides, yellow and red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be 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 medicine does not require any special storage conditions.

6.5 Nature and contents of container

The tablets are packaged in blisters of 28 tablets. The blister made of PVC/PVOC or PVC film and covered with aluminium foil.

6.6 Special precautions for disposal

This medicinal product may pose a risk to the aquatic environment. Medicines no longer required should not be disposed of via wastewater or household waste. Any unused product or waste material should be disposed of in accordance with local requirements or returned to the pharmacy.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/189/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd December 2022

10 DATE OF REVISION OF THE TEXT