Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Femoston-conti 0.5 mg/2.5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains estradiol hemihydrate equivalent to 0.5 mg estradiol and 2.5 mg dydrogesterone.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product sourced from Czech Republic:
Round, biconvex, yellow tablets marked 379 on one side.

4 CLINICAL PARTICULARS

As per PA2010/012/003

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/012/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Lactose monohydrate
Hypromellose
Maize starch
Colloidal anhydrous silica
Magnesium stearate

Film-coating:
Macrogol 3350
Polyvinyl alcohol
Talc
Titanium dioxide (E171)
Iron oxide yellow (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 blister 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

Calendar packs of 84 (3 x 28) tablets in PVC-Aluminium blister strips in a printed carton.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/464/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th February 2022

10 DATE OF REVISION OF THE TEXT