Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Premarin 0.625 mg Prolonged-release tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 0.625mg conjugated estrogens.

Excipients: Each prolonged-release tablet contains sucrose and lactose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablet.
Product imported from the UK:
Maroon, oval, biconvex, sugar-coated tablet marked with “0.625” in white ink.

4 CLINICAL PARTICULARS

As per PA 0822/095/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/095/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate
microcrystalline cellulose
magnesium stearate
hypromellose
sucrose
hydroxypropyl cellulose
macrogol
carnauba wax
edible ink and coating.

The edible ink on maroon tablets contains
hypromellose
titanium dioxide (E171)
propylene glycol (E1520).

The coating on the maroon tablets contains
hypromellose
titanium dioxide (E171)
red aluminium lake (E129)
indigo carmine (E132)
macrogol.

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

Do not store above 25°C.

6.5 Nature and contents of container

Polyvinylchloride (PVC)/Aluminium foil blisters containing 28 tablets. One carton pack contains 3 blisters.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/111/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2009

10 DATE OF REVISION OF THE TEXT

November 2014