Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Megace 40 mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of suspension contains 40 mg micronized megestrol acetate.

Excipients with known effect:
Sucrose
Sodium benzoate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

Product imported from Poland

White to cream coloured, milky suspension.

4 CLINICAL PARTICULARS

As per PA22698/024/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA22698/024/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous
Lemon-lime flavour
Polyethylene glycol 1450
Polysorbate 80
Sodium benzoate
Sodium citrate dihydrate
Sucrose
Xanthan gum
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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

High density polyethylene bottles with a child-resistant closure contained in an outer carton. Also contains a 30 ml measuring cup. Available in 240 ml pack size.

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

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd July 2020

10 DATE OF REVISION OF THE TEXT

October 2021