

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NorLevo 1.5 mg Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5 mg levonorgestrel.

Excipient with known effect: each tablet contains 90.90 mg lactose monohydrate.

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from France

White, round biconvex tablet engraved with code NL 1.5 on one face.

4 CLINICAL PARTICULARS

As per PA1166/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1166/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Povidone
Colloidal anhydrous silica
Magnesium stearate

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

Keep the blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

PVC/PE/PVDC/Aluminium blister of 1 tablet.
Pack size: 1 tablet

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/120/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2014

10 DATE OF REVISION OF THE TEXT

June 2017