Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Implanon NXT, 68 mg implant for subdermal use

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Implanon NXT is a radiopaque, non-biodegradable, progestagen-only, flexible implant preloaded in a sterile, disposable applicator.

Each radiopaque implant contains 68 mg of etonogestrel; the release rate is approximately 60-70 µg/ day in week 5-6 and has decreased to approximately 35-45 µg/ day at the end of the first year, to approximately 30-40 µg/ day at the end of the second year and to approximately 25-30 µg/ day at the end of the third year. The applicator is designed to be operated with one hand and to help facilitate correct subdermal insertion of the implant.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Implant for subdermal use

Product Imported from the Netherlands

Radiopaque, non-biodegradable, white to off-white, soft flexible rod with a length of 4 cm and 2 mm in diameter.

4 CLINICAL PARTICULARS

As per PA1286/050/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/050/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylene vinylacetate copolymer,
barium sulfate,
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 blister pack and outer packaging of the product as marketed in the country of origin.
Implanon NXT should not be inserted after the expiry date as indicated on the primary package.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

Store in the original blister package.

6.5 Nature and contents of container

Over- labelled cardboard carton containing one implant in the needle of a disposable applicator. Pack size: 1 blister pack containing one applicator and implant".

6.6 Special precautions for disposal and other handling

See section 4.2.
The applicator is for single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/108/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th May 2016

10 DATE OF REVISION OF THE TEXT