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 microgram/day in week 5-6 and has decreased to approximately 35-45 microgram/day at the end of the first year, to approximately 30-40 microgram/day at the end of the second year and to approximately 25-30 microgram/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 France.

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

Implant:
Core: Ethylene vinyl acetate copolymer (28 % vinyl acetate, 43 mg)
barium sulfate (15 mg)
magnesium stearate (0.1 mg).

Skin:
Ethylene vinyl acetate copolymer (15 % vinyl acetate, 15 mg).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 medicinal product does not require any special storage conditions.

Store in the original blister package.

6.5 Nature and contents of container

The pack contains one implant which is preloaded in the needle of a ready-for-use, disposable sterile applicator. The applicator containing the implant is packed in a blister pack.
The content of the blister pack is sterile unless the package is damaged or opened.

Pack size: 1 applicator containing 1 implant

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

See section 4.2 as per PA128650/01
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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st March 2017

10 DATE OF REVISION OF THE TEXT

October 2021