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 micrograms/day in week 5-6 and has decreased to approximately 35-45 micrograms/day at the end of the first year, to approximately 30-40 micrograms/day at the end of the second year and to approximately 25-30 micrograms/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 and Norway:
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 PA23198/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/017/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Implant
Core: Ethylene vinylacetate 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 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.
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

The blister pack contains one implant (4 cm in length and 2 mm in diameter) which is preloaded in the stainless steel needle of a ready-for-use, disposable sterile applicator. The applicator containing the implant is packed in a blister pack made of transparent polyethyleneterephthalate glycol (PETG) sealed with a lidding made of high density poly ethylene (HDPE). The content of the blister pack is sterile unless the package is damaged or opened.
Pack sizes: Carton box with 1 blister pack.

6.6 Special precautions for disposal

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.
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/171/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 2021

10 DATE OF REVISION OF THE TEXT

May 2023