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 Portugal and France
Non-biodegradable white to off-white flexible rod

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
Skin: Ethylene vinylacetate copolymer (14% vinyl acetate, 15 mg)

Product imported from France

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

The 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 polyethyleneterephtalate glycol (PETG) sealed with a lidding made of high density poly ethylene (HDPE). The content of the blister pack is sterile unless the pack is damaged or opened.

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 (Posology and Method of Administration)
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

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/250/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th May 2012
Last updated: January 2020

10 DATE OF REVISION OF THE TEXT

November 2022