Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Plus Tablets Ibuprofen 200 mg Codeine Phosphate Hemihydrate 12.8 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ibuprofen 200 mg and codeine phosphate hemihydrate 12.8 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet (Tablet)

Product imported from Poland
Nurofen Plus is a white film-coated, biconvex capsule-shaped tablet embossed with the logo 'N+' on one side.

4 CLINICAL PARTICULARS

As per PA0979/034/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/034/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from the UK
Tablet core:
Microcrystalline cellulose
Sodium starch glycolate
Starch Pregelatinised
Hypromellose

Film coating:
Hypromellose
Opaspray white M-1-7111B
Talc

Product imported from Poland
Tablet core
Microcrystalline cellulose
Sodium starch glycollate
Starch Pregelatinised
Hypromellose

Tablet coating
Hypromellose
Talc
Opaspray white M-1-7111B (containing: hypromellose and titanium dioxide (E171),)

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 carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Blister packs containing 12 or 24 tablets in a cardboard carton (OTC pack sizes).

Not all pack sizes may be marketed.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/410/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th May 2015

10 DATE OF REVISION OF THE TEXT

December 2023