

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Plus Tablets Ibuprofen 200mg Codeine Phosphate Hemihydrate 12.8mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Ibuprofen 200mg and Codeine Phosphate Hemihydrate 12.8mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet (Tablet)

Product imported from the UK:

Nurofen Plus are white, film-coated torpedo-shaped tablets embossed with 'N+' on one side and plain on the other.

4 CLINICAL PARTICULARS

As per PA0979/034/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/034/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sodium starch glycolate
Hypromellose
Pregelatinised starch
Talc
Opaspray white M-1-7111B

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips 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

Rebox containing blister strips of 12 or 24 tablets.
Pack size: 12 or 24 tablets.
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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/126/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th October 2009

10 DATE OF REVISION OF THE TEXT

November 2015