

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Cold & Flu Film-Coated Tablets
Ibuprofen 200mg
Pseudoephedrine hydrochloride 30mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains the active ingredients 200mg ibuprofen and 30mg pseudoephedrine hydrochloride.

Excipient with known effect: Sunset yellow (E110)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablets
Product imported from the UK.
Yellow, circular, biconvex, tablets printed in black with an identifying motif.

4 CLINICAL PARTICULARS

As per PA0979/033/001
This product contains sunset yellow (E110) which may cause allergic reactions.

5 PHARMACOLOGICAL PROPERTIES

As per PA0979/033/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Calcium Phosphate
Microcrystalline Cellulose
Povidone
Croscarmellose Sodium
Magnesium stearate

Film Coating:
Hypromellose
Talc
Titanium dioxide
Quinoline yellow
Sunset yellow (contains Aluminium and E110)

Black printing Ink:
Shellac
Black iron oxide (E172)
Propylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.5 Nature and contents of container

Cardboard outer containing blisters strips. Pack size of 12 or 24 tablets.

6.6 Special precautions for disposal and other handling

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

PPA1151/261/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st July 2017

10 DATE OF REVISION OF THE TEXT