

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Four Flu Film-Coated Tablets.
Paracetamol 500mg
Diphenhydramine hydrochloride 12.5mg
Pseudoephedrine hydrochloride 22.5mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Paracetamol 500mg
Diphenhydramine hydrochloride 12.5mg
Pseudoephedrine Hydrochloride 22.5mg

Excipients:Contains Sunset yellowing colouring (E110)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablets

Product imported from the UK:
Orange, biconvex, film coated tablets with no markings

4 CLINICAL PARTICULARS

As per PA0823/034/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/034/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinized maize starch
Povidone
Crospovidone
Stearic acid
Microcrystalline cellulose
Croscarmellose sodium
Magnesium Stearate

Film-coating materials

Hypromellose
Macrogol 6000
Talc
Titanium Dioxide (E171)
Sunset Yellow (E110)
Quinoline Yellow (E104)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister strip 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. Keep container in the outer carton.

6.5 Nature and contents of container

Overlabelled outer container containing blister strips

Pack size: 24 tablets

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 Ltd
Unit L2, North Ring Business Park
Santry
Dublin 9.

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/130/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th September 2009

10 DATE OF REVISION OF THE TEXT

May 2017