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 500 mg
Diphenhydramine hydrochloride 12.5 mg
Pseudoephedrine hydrochloride 22.5 mg

Also contains: Sunset yellow E110

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablets

Product imported from the UK:
Orange, oval, biconvex, film coated tablets

4 CLINICAL PARTICULARS

As per PA0823/034/002

4.4 Special warnings and precautions for use

Sunset yellow (E110) may cause allergic reactions.

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/034/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Pregelatinized maize starch
Povidone
Crospovidone
Macrogol 6000
Croscarmellose Sodium
Stearic acid
Magnesium stearate
Hypromellose
Titanium dioxide (E171)
Quinoline yellow (E104)

Sunset yellow (E110)
Talc

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. Keep container in the outer carton.

6.5 Nature and contents of container

Blister pack containing 24 tablets (two strips of 12 tablets).

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/411/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2015

10 DATE OF REVISION OF THE TEXT