

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Deltacortril Enteric 5mg gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 5mg of prednisolone.

Excipient with known effect: lactose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant tablet
Product imported from the United Kingdom:
Smooth, uniformly coloured maroon tablets

4 CLINICAL PARTICULARS

As per PA1113/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1113/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Calcium carbonate
Lactose
Magnesium stearate
Maize starch

Coating:
Polyvinyl alcohol
Titanium dioxide (E171)
Purified talc
Lecithin
Xanthan gum (E415)
Polyvinyl acetate phthalate
Polyethylene glycol
Sodium hydrogen carbonate
Triethyl citrate
Purified stearic acid
Sodium alginate (E401)
Colloidal silicon dioxide
Lactose monohydrate
Methylcellulose (E461)
Sodium carboxymethyl cellulose
Carmine (E120)

Indigo carmine aluminium lake (E132)
Beeswax (E901)
Carnauba wax (E903)
Polysorbate 20 (E432)
Sorbic acid (E200)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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.

6.5 Nature and contents of container

Outer carton containing blister strips.
Pack size: 30 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 Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/213/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd January 2015

10 DATE OF REVISION OF THE TEXT

February 2018