

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Entocort CR 3 mg Gastro-resistant Capsule, Hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains budesonide 3 mg.

Excipient with known effect: sucrose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant, prolonged release capsules, hard.

The product imported from Greece and Belgium:

Hard gelatin capsules with an opaque, light grey body and opaque, pink cap marked 'CIR 3 mg' in black radial print.

4 CLINICAL PARTICULARS

As per PA2018/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2018/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The product imported from Greece contains:

Ethyl cellulose
Tributyl acetyl citrate
Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent
Triethyl citrate
Simethicone (Antifoam M)
Polysorbate 80
Talc
Sugar spheres (consisting of sucrose and maize starch).

Capsule shell:
Black iron oxide (E172)
Titanium dioxide (E171)
Gelatine

Red iron oxide (E172)
Yellow iron oxide (E172)

The product imported from Belgium contains:

Ethylcellulose
Tributyl acetylcitrate
Methacrylic acid Copolymer C

Triethyl citrate
Antifoam M
Polysorbate 80
Talc
Sucrose spheres

Capsule shell:
Black iron oxide (E172)
Titanium dioxide (E171)
Gelatin
Sodium lauril sulfate
Colloidal anhydrous silica

Red iron oxide (E172)
Yellow iron oxide (E172)
Ink (der. 41/370-42/1015)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30 °C. Store in the original package.
Keep the container tightly closed.

6.5 Nature and contents of container

Product imported from Greece:

White, polyethylene bottles of 50 capsules, having a tamper evident, childproof polypropylene screw cap, with an integral desiccant. 2 bottles containing 50 capsules each will be repackaged into a box containing 100 capsules.

Product imported from Belgium:

White, polyethylene bottle of 100 capsules, having an integral desiccant.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/467/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2021

10 DATE OF REVISION OF THE TEXT

November 2023