

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.

Product imported from *Belgium*

Hard gelatin capsules with an opaque, light grey body and opaque, pink cap marked **CIR 3mg** 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

Ethylcellulose
Tributyl acetylcitrate
Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent
Triethyl citrate
Simeticone (Antifoam M) Polysorbate 80
Talc
Sucrose spheres

Capsule shell:
Black iron oxide (E172) Titanium dioxide (E171) Gelatin
Sodium laurilsulfate 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 container 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

White, polyethylene bottles of 100 capsules, having a tamper-evident, childproof polypropylene screw cap, with an integral desiccant.

6.6 Special precautions for disposal

White, polyethylene bottles of 100 capsules, having a tamper-evident, childproof polypropylene screw cap, with an integral desiccant.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/178/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd July 2021

10 DATE OF REVISION OF THE TEXT