

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Septrin 80 mg/400 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 80 mg trimethoprim and 400 mg sulfamethoxazole.

Excipient(s) with known effect: sodium

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Spain:

White, round, biconvex tablets, with a score line on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1691/010/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1691/010/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycolate type A

Povidone K30

Docusate sodium

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 25°C.

Keep the blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

PVC/Aluminium foil blister packs.

Packs of 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/234/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th December 2024

10 DATE OF REVISION OF THE TEXT