Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zarontin 250 mg/5 ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains ethosuximide 250 mg.

Excipients with known effect:
Each 5ml contains 3 g sucrose, 5 mg glucose, 12 mg sodium benzoate (E211) and 42 mg propylene glycol (E1520).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

Product imported from France and Italy:
A clear, slightly yellowish to slightly pinkish, dye-free, raspberry flavoured syrup.

4 CLINICAL PARTICULARS

As per PA22644/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22644/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate dihydrate
Sodium benzoate (E211)
Saccharin sodium
Sucrose
Glycerol
Artificial Raspberry flavour including glucose and propylene glycol (E1520)
Citric acid monohydrate
Purified water

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 25 °C.

6.5 Nature and contents of container

200 ml amber glass bottle with a child-resistant cap and measuring cup graduated from 2 ml to 15 ml.

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

PPA0465/456/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th September 2020

10 DATE OF REVISION OF THE TEXT

January 2024