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:

Product imported from *Belgium:*
Contains sucrose, glucose and sodium benzoate (E211).

Product imported from *France:*
Contains sucrose, glucose, sodium benzoate and 42 mg propylene glycol in each 5 ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

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

4 CLINICAL PARTICULARS

As per PA22644/005/001
Product imported from France contains *propylene glycol (E 1520):*
This medicinal product contains 42 mg of propylene glycol per 5 mL equivalent to 8.4 mg/mL. Concomitant administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates.

5 PHARMACOLOGICAL PROPERTIES

As per PA22644/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Belgium:
sodium citrate
sodium benzoate (E211)
saccharin sodium
sucrose
glycerol
raspberry flavour including glucose
citric acid monohydrate
purified water

Product imported from France:
sodium citrate dihydrate
sodium benzoate (E 211)
sodium saccharin
sucrose
glycerol (E 422)

artificial raspberry flavour (including glucose and propylene glycol (E 1520))
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

Amber glass bottle with a white aluminium cap and a 15 ml graduated measuring cup. Each unit contains 200 ml and is placed in a folding carton.

6.6 Special precautions for disposal and other handling

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

PPA1463/181/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd July 2021

10 DATE OF REVISION OF THE TEXT

March 2023