Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zarontin 250mg/5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 250 mg ethosuximide.

Excipients with known effect:
Each 5 ml 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 Belgium.

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
Sodium benzoate (E211)
Saccharin sodium
Sucrose
Glycerol
Raspberry flavour including (contains 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 for 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 child-resistant cap. Each unit contains 200 ml and is placed in folding carton with a measuring cup graduated 15 ml.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th January 2024

10 DATE OF REVISION OF THE TEXT