Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zarontin 250 mg/5 ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syrup contains 250 mg ethosuximide.

Excipients with known effect:
Contains sucrose, glucose, sodium benzoate (E211) & Propylene glycol (E 1520).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.

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

4 CLINICAL PARTICULARS

As per PA22644/005/001

Product imported from Italy contains *propylene glycol (E 1520):*

This medicinal product contains 42 mg of propylene glycol per 5 ml equivalent to 8.4 mg/ml.
Co-administration with any alcohol dehydrogenase substrate such as ethanol can induce serious adverse effects in infants.

Although propylene glycol has shown no toxic effects on reproduction and development in animals either humans, can reach the fetus and has been found in mothers's milk. As a consequence, the administration of propylene glycol to pregnant or lactating patients should be considered on a case-by-case basis.

Clinical monitoring is required for patients with hepatic or renal insufficiency due to various adverse events attributed to propylene glycol such as renal dysfunction (acute tubular necrosis), injury acute kidney and liver dysfunction.

5 PHARMACOLOGICAL PROPERTIES

As per PA22644/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate
Sodium benzoate (E211)
Citric acid monohydrate
Glycerol
Sucrose
Raspberry flavour (including glucose and propylene glycol)
Saccharin sodium
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 a white aluminium or child-resistant cap. Each unit contains 200 ml and is placed in folding carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation date: 24th June 2022

10 DATE OF REVISION OF THE TEXT

April 2023