

# 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:

Contains sucrose, glucose and sodium benzoate (E211).

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

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

Donot store above 25°C.

**6.5 Nature and contents of container**

Amber glass bottle with a child-resistant cap and measuring cup.

**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: 18<sup>th</sup> September 2020

**10 DATE OF REVISION OF THE TEXT**

April 2021