# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zofran 4 mg/5 ml syrup

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 4 mg ondansetron (as ondansetron hydrochloride dihydrate).

Excipients with known effect: Sorbitol, ethanol and sodium benzoate.

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Oral solution.

*Product imported from Poland:*
Clear, colourless to light yellow liquid with characteristic strawberry odour.

## 4 CLINICAL PARTICULARS

As per PA0711/327/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0711/327/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid anhydrous (E330)
Sodium citrate dihydrate
Sodium benzoate (E211)
Sorbitol 70% (crystallising) (E420)
Strawberry flavour*
Purified Water

*Strawberry flavour contains small amounts of ethanol (alcohol)

### 6.2 Incompatibilities

Due to the lack of available data, Zofran Syrup should not be diluted or admixed with any other liquid preparation.

### 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. The product should be used within 28 days after first opening.

### 6.4 Special precautions for storage

Zofran Syrup should be stored upright. Do not store above 25°C. Do not refrigerate or freeze.

**6.5 Nature and contents of container**

Zofran Syrup is packed into a 60 ml amber glass bottle, with a child resistant cap. Bottles contain 50 ml.

**6.6 Special precautions for disposal**

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/113/005

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 16th April 2021

**10 DATE OF REVISION OF THE TEXT**

May 2023