

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran 4 mg/5 ml syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect:

Each 5 ml also contains Sorbitol (E420), 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 PA0896/036/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/036/003

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 is the date shown on the container and outer package of the product on the market in the country of origin.

This 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 Ph. Eur. Type III amber glass bottle, with a child resistant cap. Bottles contain 50 ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/158/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th February 2021

10 DATE OF REVISION OF THE TEXT