

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zofran 4 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 4 mg ondansetron (as hydrochloride dihydrate).

Excipient(s) with known effect: lactose anhydrous

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Greece*

Yellow, oval, biconvex tablets engraved GXET3 on one face and plain on the other face.

## 4 CLINICAL PARTICULARS

As per PA0711/327/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0711/327/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Core

Lactose anhydrous

Microcrystalline cellulose

Pregelatinised maize starch

Magnesium stearate

#### Film Coating

Hypromellose

Opaspray Yellow M-1-8429

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Store below 30°C.

### 6.5 Nature and contents of container

Blister packs of PVC/aluminium containing 15 film-coated tablets.

**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**

Swallow whole with a glass of water.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/158/002

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

Date of first authorisation: 25<sup>th</sup> March 2022

**10 DATE OF REVISION OF THE TEXT**

April 2023