Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran 8 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 8 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 GXET5 on one face and plain on the other face.

4 CLINICAL PARTICULARS

As per PA0896/036/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/036/006

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

PPA1463/158/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th March 2022

10 DATE OF REVISION OF THE TEXT