Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran 4 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ondansetron 4mg as ondansetron hydrochloride dihydrate.

Excipients: Contains Lactose Anhydrous 81.875mg
For a full list of exciptents, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Poland
Yellow, oval, biconvex tablets "GXET3" on the face and plain on the other face

4 CLINICAL PARTICULARS

As per PA0013/125/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/125/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Lactose Anhydrous
Microcrystalline cellulose
Pregelatanised maize starch
Magnesium stearate

Film Coating
Hypromellose
Titanium dioxide (E171)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Zofran film-coated tablets are available in blister packs containing 10 tablets in an over-labelled outer carton.

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd June 2012

10 DATE OF REVISION OF THE TEXT

April 2018