Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran 8 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg ondansetron as hydrochloride dihydrate.

Excipient(s) with known effect: Lactose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Product imported from Hungary, Poland and Greece:
Film-coated tablet.
Yellow, oval, film coated tablet engraved 'GLAXO' on one face and '8' on the other
or
Yellow, oval, film coated tablet engraved 'GX ET 5' on one side and blank on the other.

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
Microcrystalline cellulose
Maize starch
Magnesium stearate

Film-coating:
Hypromellose
Titanium dioxide (E171)
Iron oxide (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 package 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

Blister pack containing 10, 15 or 30 tablets contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/113/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 October 2003

Date of last renewal: 17 October 2008

10 DATE OF REVISION OF THE TEXT

July 2020