Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran 8 mg Film-coated Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ondansetron 8mg as ondansetron hydrochloride dihydrate.

Excipient: contains lactose anhydrous.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from Poland:
Yellow, biconvex, oval film-coated tablet engraved “GXET5” on one face and plain on the other.

4 CLINICAL PARTICULARS

As per PA1077/016/006.

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/016/006.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Lactose anhydrous
Microcrystalline cellulose
Pregelatinised 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 shall be the date shown on the blister 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

Zofran tablets are available in double foil blister packs containing 5 tablets per strip in a cardboard carton. Total pack size 10 tablets.

6.6 Special precautions for disposal and other handling

Swallow whole with a glass of water.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/148/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd May 2011

10 DATE OF REVISION OF THE TEXT

March 2015