Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zofran Zydis 4 mg oral lyophilisate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Zofran Zydis oral lyophilisate contains 4 mg ondansetron.

Excipient(s) with known effect: Each 4mg Oral Lyophilisate contains aspartame (E951), sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) and 0.0015 mg of ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral lyophilisate

Product imported from Spain:
White round oral lyophilisate.

4 CLINICAL PARTICULARS

As per PA0711/327/005

4.4 Special warnings and precautions for use

Zofran Zydis 4 mg tablet contains less than 0.0015 mg of alcohol (ethanol) in each 4 mg Oral lyophilisate tablet which is equivalent to 0.1 % w/w.
The amount in one tablet of this medicine is equivalent to less than 1 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

5 PHARMACOLOGICAL PROPERTIES

As per PA0711/327/005

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Mannitol (E421)
Aspartame (E951)
Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Strawberry flavour. The strawberry flavour has the following composition: artificial flavouring substances, natural flavouring substances and propylene glycol (E1520)

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

Do not store above 30 °C
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Double foil blister packs contained in an outer cardboard carton. Blisters of 10 Zofran Zydis oral lyophilisate dosage units.

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

DO NOT attempt to push Zofran Zydis through the lidding foil. PEEL BACK the lidding foil of one blister and GENTLY remove the Zofran Zydis. Place the Zofran Zydis on top of the tongue, where it will disperse within seconds, then swallow.
Any unused product should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/445/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st May 2019

10 DATE OF REVISION OF THE TEXT

December 2023