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 4 mg oral lyophilisate contains aspartame (E951), sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217).
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 PA0896/036/007

5 PHARMACOLOGICAL PROPERTIES

As per PA0896/036/007

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Mannitol (E421)
Aspartame (E951)
Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Strawberry flavour (contains natural flavouring substances, artificial flavouring substances, 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 carton of the product as marketed 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.
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

Originalis B.V.
Joop Geesinkenweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2018

10 DATE OF REVISION OF THE TEXT