

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**BOX x 50 ampoules x 2 mL [4 mL]**

**1. NAME OF THE MEDICINAL PRODUCT**

Zophralen 4 mg/2 mL Solution for Injection  
[Zophralen 8 mg/4 mL Solution for Injection]

Ondansetron

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each 2 mL [4 mL] ampoule contains ondansetron hydrochloride dihydrate equivalent to 4 mg [8 mg] of ondansetron.

**3. LIST OF EXCIPIENTS**

Citric acid monohydrate, sodium citrate dihydrate, sodium chloride and water for injections.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for Injection

50 x 2 mL [4 mL] Amp

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous or intramuscular administration

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**8. EXPIRY DATE**

EXP: XXXX

**9. SPECIAL STORAGE CONDITIONS**

Store below 25°C.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

DEMO S.A. Pharmaceutical Industry  
21<sup>st</sup> km National Road Athens – Lamia, 145 68 Krioneri, Attiki, Greece  
Tel.: +30 (210) 81 61 802  
Fax: +30 (210) 81 61 587

**12. MARKETING AUTHORISATION NUMBER(S)**

4 mg/2 mL: 40893/09/19-02-2010 GR  
[8 mg/4 mL: 40895/09/19-02-2010] GR

**13. BATCH NUMBER**

LOT: XXXXXXXX

**14. GENERAL CLASSIFICATION FOR SUPPLY**

General classification for supply in Greece. By limited medical prescription. For hospital use only

**15. INSTRUCTIONS ON USE**



**16. INFORMATION IN BRAILLE**

Not applicable

**17. UNIQUE IDENTIFIER – 2D BARCODE**

Not applicable

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

Not applicable

Ondansetron  
(as hydrochloride dihydrate)  
8 mg/4 mL solution for injection  
(DEMO S.A.), HA607

WHOPAR part 5  
supplier's submission

September 2024

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

ampoule of 2 mL [4 mL]

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

Zophralen 4 mg/2 mL  
[Zophralen 8 mg/4 mL ]

Ondansetron

**2. METHOD OF ADMINISTRATION**

IV/IM

**3. EXPIRY DATE**

EXP: XXXX

**4. BATCH NUMBER**

LOT: XXXXXXXX

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

2 mL  
4 mL

**6. OTHER**

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Ondansetron  
(as hydrochloride dihydrate)  
8 mg/4 mL solution for injection  
(DEMO S.A.), HA607

WHOPAR part 5  
supplier's submission

September 2024

**MINIMUM PARTICULARS TO APPEAR ON INTERMEDIATE PACKAGING UNITS**

foil of 2 mL [4 mL]

**. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

Zophralen 4 mg/2 mL solution for injection  
[Zophralen 8 mg/4 mL solution for injection]

Ondansetron

**2. METHOD OF ADMINISTRATION**

IV/IM

**3. EXPIRY DATE**

EXP: XXXX

**4. BATCH NUMBER**

LOT: XXXXXXXX

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

2 mL  
4 mL

**6. OTHER**

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**7. NAME OF THE MARKETING AUTHORISATION HOLDER**

DEMO S.A. Pharmaceutical Industry