PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX x 1 plastic ampoule x 2ml [4ml]

1. NAME OF THE MEDICINAL PRODUCT

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

Ondansetron

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 2ml [4ml] plastic ampoule contains 4mg [8mg] of ondansetron (as hydrochloride dihydrate)

3. LIST OF EXCIPIENTS

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

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Injection

1 x 2ml [4ml] plastic ampoule

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular use.
For single use. Discard any unused portion.
Read the package leaflet before use.

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

8. EXPIRY DATE

EXP: XXXX

From a microbiological point of view, unless the method of opening or dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

9. SPECIAL STORAGE CONDITIONS

Store below 25ºC. Store in the original package in order to protect from light.

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
21st km National Road Athens – Lamia, 145 68 Krioneri Attica, 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
[8 mg/4 mL: 40895/09/19-02-2010]

13. BATCH NUMBER

14. GENERAL CLASSIFICATION FOR SUPPLY

By limited medicinal prescription: For hospital use only

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

plastic ampoule of 2ml [4ml]

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

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

2. METHOD OF ADMINISTRATION

For intravenous or intramuscular use

3. EXPIRY DATE

EXP: XXXX

4. BATCH NUMBER

LOT: XXXX

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

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

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX x 1 glass ampoule x 2ml [4ml]

1. NAME OF THE MEDICINAL PRODUCT

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

Ondansetron

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 2ml [4ml] glass ampoule contains 4mg [8mg] of ondansetron (as hydrochloride dihydrate)

3. LIST OF EXCIPIENTS

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

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Injection

1 x 2ml [4ml] glass ampoule

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular use.
For single use. Discard any unused portion.
Read the package leaflet before use.

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

8. EXPIRY DATE

EXP: XXXX

From a microbiological point of view, unless the method of opening or dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

9. SPECIAL STORAGE CONDITIONS

Store below 25ºC. Store in the original package in order to protect from light.

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

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13. BATCH NUMBER

14. GENERAL CLASSIFICATION FOR SUPPLY

By limited medicinal prescription: For hospital use only

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

glass ampoule of 2ml [4ml]

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

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

2. METHOD OF ADMINISTRATION

For intravenous or intramuscular use

3. EXPIRY DATE

EXP: XXXX

4. BATCH NUMBER

LOT: XXXX

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

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

6. OTHER