PARTICULARS TO APPEAR ON THE OUTER PACKAGING CARTON OF UNIT PACK - pre-filled pen 1. NAME OF THE MEDICINAL PRODUCT Aimovig 140 mg solution for injection in pre-filled pen erenumab 2. STATEMENT OF ACTIVE SUBSTANCE(S) One pre-filled pen contains 140 mg erenumab. **3.** LIST OF EXCIPIENTS Also contains: sucrose, polysorbate 80, sodium hydroxide, glacial acetic acid, water for injections. Needle cap contains latex. 4. PHARMACEUTICAL FORM AND CONTENTS Solution for injection 1 pre-filled pen 5. METHOD AND ROUTE(S) OF ADMINISTRATION Read the package leaflet before use. Subcutaneous use Single 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**

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

| 10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PROD OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS APPROPRIATE | |
|---|--|
| 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER | |
| Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland | |
| 12. MARKETING AUTHORISATION NUMBER(S) | |
| EU/1/18/1293/004 Pack containing 1 pre-filled pen | |
| 13. BATCH NUMBER | |
| Lot | |
| 14. GENERAL CLASSIFICATION FOR SUPPLY | |
| | |
| 15. INSTRUCTIONS ON USE | |
| | |
| 16. INFORMATION IN BRAILLE | |
| Aimovig 140 mg | |
| 17. UNIQUE IDENTIFIER – 2D BARCODE | |
| 2D barcode carrying the unique identifier included. | |
| 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA | |
| PC SN NN | |

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON OF MULTIPACK (INCLUDING BLUE BOX) - pre-filled pen

1. NAME OF THE MEDICINAL PRODUCT

Aimovig 140 mg solution for injection in pre-filled pen erenumab

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled pen contains 140 mg erenumab.

3. LIST OF EXCIPIENTS

Also contains: sucrose, polysorbate 80, sodium hydroxide, glacial acetic acid, water for injections. Needle cap contains latex.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multipack: 3 (3 packs of 1) pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Subcutaneous use

Single 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

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

Keep the pre-filled pens in the outer carton in order to protect from light.

| 10. | OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE |
|-------|---|
| | |
| 11. | NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
| Vista | |
| 12. | MARKETING AUTHORISATION NUMBER(S) |
| EU/ | 1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens |
| 13. | BATCH NUMBER |
| Lot | |
| 14. | GENERAL CLASSIFICATION FOR SUPPLY |
| | |
| 15. | INSTRUCTIONS ON USE |
| | |
| 16. | INFORMATION IN BRAILLE |
| Aimo | ovig 140 mg |
| 17. | UNIQUE IDENTIFIER – 2D BARCODE |
| 2D b | arcode carrying the unique identifier included. |
| 18. | UNIQUE IDENTIFIER - HUMAN READABLE DATA |
| PC | |
| SN | |
| NN | |
| | |

PARTICULARS TO APPEAR ON THE OUTER PACKAGING INTERMEDIATE CARTON OF MULTIPACK (WITHOUT BLUE BOX) - pre-filled pen 1. NAME OF THE MEDICINAL PRODUCT Aimovig 140 mg solution for injection in pre-filled pen erenumab 2. STATEMENT OF ACTIVE SUBSTANCE(S) One pre-filled pen contains 140 mg erenumab. **3.** LIST OF EXCIPIENTS Also contains: sucrose, polysorbate 80, sodium hydroxide, glacial acetic acid, water for injections. Needle cap contains latex. 4. PHARMACEUTICAL FORM AND CONTENTS Solution for injection 1 pre-filled pen Component of a multipack. Not to be sold separately. 5. METHOD AND ROUTE(S) OF ADMINISTRATION Read the package leaflet before use. Subcutaneous use Single use. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT 6.

Keep out of the sight and reach of children.

OF THE SIGHT AND REACH OF CHILDREN

OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

7.

| Store in a refrigerator. Do not freeze. Keep the pre-filled pen in the outer carton 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 Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland 12. MARKETING AUTHORISATION NUMBER(S) EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER - 2D BARCODE | 9. | SPECIAL STORAGE CONDITIONS |
|---|----------------------|--|
| OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE 11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland 12. MARKETING AUTHORISATION NUMBER(S) EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | | |
| Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland 12. MARKETING AUTHORISATION NUMBER(S) EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 10. | OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF |
| Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland 12. MARKETING AUTHORISATION NUMBER(S) EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | | |
| Vista Building Elm Park, Merrion Road Dublin 4 Ireland 12. MARKETING AUTHORISATION NUMBER(S) EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 11. | NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER |
| EU/1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | Vista Elm Dubl | a Building Park, Merrion Road lin 4 |
| 13. BATCH NUMBER Lot 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 12. | MARKETING AUTHORISATION NUMBER(S) |
| 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | EU | /1/18/1293/005 Multipack containing 3 (3x 1) pre-filled pens |
| 14. GENERAL CLASSIFICATION FOR SUPPLY 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 13. | BATCH NUMBER |
| 15. INSTRUCTIONS ON USE 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | Lot | |
| 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 14. | GENERAL CLASSIFICATION FOR SUPPLY |
| 16. INFORMATION IN BRAILLE Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | | |
| Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | 15. | INSTRUCTIONS ON USE |
| Aimovig 140 mg 17. UNIQUE IDENTIFIER – 2D BARCODE | | |
| 17. UNIQUE IDENTIFIER – 2D BARCODE | 16. | INFORMATION IN BRAILLE |
| | Aim | ovig 140 mg |
| 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA | 17. | UNIQUE IDENTIFIER – 2D BARCODE |
| 18. UNIQUE IDENTIFIER - HUMAN READABLE DATA | | |
| | 18. | UNIQUE IDENTIFIER - HUMAN READABLE DATA |

| MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS | | |
|--|--|--|
| PEN LABEL | | |
| | | |
| 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION | | |
| Aimovig 140 mg injection erenumab SC | | |
| 2. METHOD OF ADMINISTRATION | | |
| 2. METHOD OF ADMINISTRATION | | |
| 3. EXPIRY DATE | | |
| EXP | | |
| 4. BATCH NUMBER | | |
| Lot | | |
| 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT | | |
| | | |
| 6. OTHER | | |