

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX – UNIT PACKAGING – BOX OF 1 VIAL + 1 AMPOULE

1. NAME OF THE MEDICINAL PRODUCT

BENZETACIL 1,200,000 IU powder and solvent for suspension for injection
Benzathine benzylpenicillin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 1,200,000 IU of benzathine benzylpenicillin
Each ampoule contains 4 ml of water for injection.

3. LIST OF EXCIPIENTS

Vial:
Excipients: Tween 80, lecithin, sodium citrate (E-331).

Read the package leaflet for more information.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for suspension for injection
1 vial and 1 ampoule of solvent

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep intramuscular route exclusively.

Read the package leaflet before use.

TO INJECT BENZETACIL:

- 1) Introduce the solvent into the vial. Shake until a homogeneous suspension is obtained. Remove the suspension of the vial with the syringe.
- 2) To inject, use a different needle than the one used to extract the suspension from the vial. The needle should have a 0.9 mm of calibre, long for adults and short for children. Stick the needle into the patient.
- 3) Place the syringe on the needle and aspirate to check that no blood comes out.
- 4) Inject as soon as possible.

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 dry place.

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

Laboratorio Reig Jofré, S.A.
Gran Capitán, 10
08970 Sant Joan Despí (Barcelona)
España

12. MARKETING AUTHORISATION NUMBER(S)

13. LOT NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

MEDICAL PRESCRIPTION

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

benze-tacil m 1,2

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA
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PC {number} [product code]

SN {number} [serial number]

NN {number} [national reimbursement number or other national number identifying the medicinal product]>

19. OTHERS

Medical prescription

symbol ○

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

UNIT PACKAGING OF CLINICAL PACK

1. NAME OF THE MEDICINAL PRODUCT

BENZETACIL 1,200,000 IU powder and solvent for suspension for injection
Benzathine benzylpenicillin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 1,200,000 IU of benzathine benzylpenicillin
Each ampoule contains 4 ml of water for injection.

3. LIST OF EXCIPIENTS

Vial:
Excipients: Tween 80, lecithin, sodium citrate (E-331).

Read the package leaflet for more information

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for suspension for injection

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep intramuscular route exclusively.

Read the package leaflet before use.

TO INJECT BENZETACIL:

- 1) Introduce the solvent into the vial. Shake until a homogeneous suspension is obtained. Remove the suspension of the vial into the syringe.
- 2) To inject, use a different needle than the one used to extract the suspension from the vial. The needle should have a 0.9 mm of calibre, long for adults and short for children. Stick the needle into de patient.
- 3) Place the syringe on the needle and aspirate to check that no blood comes out.
- 4) Inject as soon as possible.

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

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

Laboratorio Reig Jofré, S.A.
Gran Capitán, 10
08970 Sant Joan Despí (Barcelona)
España
Logotype Reig Jofré

12. MARKETING AUTHORISATION NUMBER(S)

13. LOT NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

MEDICAL PRESCRIPTION

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. NATIONAL CODE AND SYMBOLS

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Sigre symbol

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER LABEL CLINICAL PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

BENZETACIL 1,200,000 IU powder and solvent for suspension for injection
Benzathine benzylpenicillin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains:

Benzathine benzylpenicillin 1,200,000 IU

Each ampoule contains 4 ml of water for injection.

3. LIST OF EXCIPIENTS

Vial:

Excipients: Tween 80, lecithin, sodium citrate (E-331).

4. PHARMACEUTICAL FORM AND CONTENTS

100 vials and 100 ampoules of solvent.

Powder and solvent for suspension for injection

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep intramuscular route exclusively.

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

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

Laboratorio Reig Jofré, S.A.
Gran Capitán, 10
08970 Sant Joan Despí (Barcelona)
España

12. MARKETING AUTHORISATION NUMBER(S)

13. LOT NUMBER

LOT:

14. GENERAL CLASSIFICATION FOR SUPPLY

MEDICAL PRESCRIPTION

**CLINICAL PACKAGING
NOT FOR SALE IN RETAIL**

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC {number} [product code]
SN {number} [serial number]
NN {number} [national reimbursement number or other national number identifying the medicinal product]>

19. OTHERS

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABELLING

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

BENZETACIL 1,200,000 IU powder and solvent for suspension for injection
Benzathine benzylpenicillin

2. METHOD OF ADMINISTRATION

Deep intramuscular route exclusively.

3. EXPIRY DATE

EXP:

4. LOT NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

LABORATORIO REIG JOFRE , S.A

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE SERYGRAPH

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

Water for injections

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. LOT NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

4 ml

6. OTHER

LAB. REIG JOFRE , S.A