

1.3.2.1 English labelling

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BAG LABELS

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 1,36% w/v / 13,6 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	A + B g/l
Glucose monohydrate	15,0
equivalent to Glucose anhydrous	13,6
Calcium chloride dihydrate	0,257
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,67
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,12

	A + B (mmol/l)
C ₆ H ₁₂ O ₆	75,5
Na ⁺	132
Ca ⁺⁺	1,75
Mg ⁺⁺	0,25
Cl ⁻	101
HCO ₃ ⁻	25
C ₃ H ₅ O ₃ ⁻	10

Osmolarity 345 mOsmol/l
pH 7,4

A ≈ <volume> ml B ≈ <volume> ml

3. LIST OF EXCIPIENTS

Water for Injections, Sodium hydroxide, Hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Peritoneal Dialysis
<Single /Twin> two chamber bag with Luer connector
<volume> ml
Free from bacterial endotoxin

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Intraperitoneal use only
Not for intravenous infusion
Once removed from its overpouch and mixed, the product should be used within 24 hours.

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

Use as directed by your physician
Do not administer unless the solution is clear and the container undamaged
Open long-seal first, then open short-seal before infusing the solution. Infusion of unmixed solution can cause abdominal pain and may cause severe side effects if not drained immediately
For single use only
Discard unused solution

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store below 4°C

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

NA

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd., Caxton Way, Thetford, IP24 3SE United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0408

13. BATCH NUMBER

Lot {number}
<Manufactured by Baxter Healthcare SA IRL-Castlebar> or
<Manufactured by Bieffe Medital S.p.A, Grosotto Italy>

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

NA

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 2,27% w/v / 22,7 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	A + B g/l
Glucose monohydrate	25,0
Equivalent to Glucose anhydrous	22,7
Calcium chloride dihydrate	0,257
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,67
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,12

	A + B (mmol/l)
C ₆ H ₁₂ O ₆	126
Na ⁺	132
Ca ⁺⁺	1,75
Mg ⁺⁺	0,25
Cl ⁻	101
HCO ₃ ⁻	25
C ₃ H ₅ O ₃ ⁻	10

Osmolarity 396 mOsmol/l
pH 7,4

A ≈ <volume> ml B ≈ <volume> ml

3. LIST OF EXCIPIENTS

Water for Injections, Sodium hydroxide, Hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Peritoneal Dialysis
<Single / Twin> two chamber bag with Luer connector
<volume> ml
Free from bacterial endotoxin

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
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6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

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For single use only
Discard unused solution

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store below 4°C

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

NA

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd., Caxton Way, Thetford, IP24 3SE United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0409

13. BATCH NUMBER

Lot {number}
<Manufactured by Baxter Healthcare SA IRL-Castlebar> or
<Manufactured by Bieffe Medital S.p.A, Grosotto Italy>

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

NA

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 3,86% w/v / 38,6 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	A + B g/l
Glucose monohydrate	42,5
Equivalent to Glucose anhydrous	38,6
Calcium chloride dihydrate	0,257
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,67
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,12

	A + B (mmol/l)
C ₆ H ₁₂ O ₆	214
Na ⁺	132
Ca ⁺⁺	1,75
Mg ⁺⁺	0,25
Cl ⁻	101
HCO ₃ ⁻	25
C ₃ H ₅ O ₃ ⁻	10

Osmolarity 484 mOsmol/l
pH 7,4

A ≈ <volume> ml B ≈ <volume> ml

3. LIST OF EXCIPIENTS

Water for Injections, Sodium hydroxide, Hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Peritoneal Dialysis
<Single / Twin> two chamber bag with Luer connector
<volume> ml
Free from bacterial endotoxin

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Intraperitoneal use only
Not for intravenous infusion
Once removed from its overpouch and mixed, the product should be used within 24 hours

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

Use as directed by your physician

Do not administer unless the solution is clear and the container is undamaged

Open long-seal first, then open short-seal before infusing the solution. Infusion of unmixed solution can cause abdominal pain and may cause severe side effects if not drained immediately

For single use only

Discard unused solution

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store below 4°C

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

NA

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd., Caxton Way, Thetford, IP24 3SE United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0410

13. BATCH NUMBER

Lot {number}

<Manufactured by Baxter Healthcare SA IRL-Castlebar> or

<Manufactured by Bieffe Medital S.p.A, Grosotto Italy>

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

NA

PARTICULARS TO APPEAR ON OUTER PACKAGING: CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 1,36% w/v / 13,6 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	(g/l)
Glucose monohydrate	15,0
Equivalent to Glucose anhydrous	13,6
Sodium chloride	5,67
Calcium chloride dihydrate	0,257
Magnesium chloride hexahydrate	0,051
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,12
Osmolarity 345 mOsmol/l	

3. LIST OF EXCIPIENTS

Water for injections, Sodium hydroxide, Hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Peritoneal Dialysis
<Single / Twin> two chamber bag with Luer connector
<volume> ml x <pack size>

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal use
Read the package leaflet

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

NA

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store below 4°C

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

NA

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd., Caxton Way, Thetford, IP24 3SE United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0408

13. BATCH NUMBER

Lot {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

NA

16. INFORMATION IN BRAILLE (to appear on a separate label on the carton box)

Physioneal 35 Glucose 1,36% w/v / 13,6 mg/ml Clear-Flex

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}

SN: {number}

NN: {number}

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 35 Glucose 2,27% w/v / 22,7 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	(g/l)
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Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1.12
Osmolarity 396 mOsmol/l	

3. LIST OF EXCIPIENTS

Water for injections, Sodium hydroxide, Hydrochloric acid

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for Peritoneal Dialysis
<Single / Twin> two chamber bag with Luer connector
<volume> ml x <pack size>

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal use
Read the package leaflet

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

NA

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store below 4°C

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

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11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd., Caxton Way, Thetford, IP24 3SE United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0409

13. BATCH NUMBER

Lot{number}

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

NA

16. INFORMATION IN BRAILLE (to appear on a separate label on the carton box)

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