

1.3.2.1 English labelling

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BAG LABELS

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 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	0,184
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,38
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,68

	A + B (mmol/l)
$C_6H_{12}O_6$	75,5
Na^+	132
Ca^{++}	1,25
Mg^{++}	0,25
Cl^-	95
HCO_3^-	25
$C_3H_5O_3^-$	15

Osmolarity 344 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 / Spike / Lineo> 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 00116/0411

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

NA

16. INFORMATION IN BRAILLE

NA

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 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	0,184
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,38
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,68

	A + B (mmol/l)
C ₆ H ₁₂ O ₆	126
Na ⁺	132
Ca ⁺⁺	1,25
Mg ⁺⁺	0,25
Cl ⁻	95
HCO ₃ ⁻	25
C ₃ H ₅ O ₃ ⁻	15

Osmolarity 395 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 / Spike / Lineo> 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 00116/0412

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

NA

16. INFORMATION IN BRAILLE

NA

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 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	0,184
Magnesium chloride hexahydrate	0,051
Sodium chloride	5,38
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,68

	A + B (mmol/l)
C ₆ H ₁₂ O ₆	214
Na ⁺	132
Ca ⁺⁺	1,25
Mg ⁺⁺	0,25
Cl ⁻	95
HCO ₃ ⁻	25
C ₃ H ₅ O ₃ ⁻	15

Osmolarity 483 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 / Spike / Lineo> 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 00116/0413

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

NA

16. INFORMATION IN BRAILLE

NA

PARTICULARS TO APPEAR ON OUTER PACKAGING: CARTON BOX

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 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	5,38
Calcium chloride dihydrate	0,184
Magnesium chloride hexahydrate	0,051
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,68
Osmolarity	344 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 / spike / lineo> connector
<volume> ml x <pack size>

For HomeChoice APD set only available in Denmark, Iceland, Finland, Norway and Sweden:

<Combination package>

<Contains accessories: 1xXXXXXXXX¹ HomeChoice lineset, 1xXXXXXXXX¹ MiniCap and 1xXXXXXXXX¹ Connector protection>

¹Information on product code

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 00116/0411

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

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 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)
Glucose monohydrate	25.0
Equivalent to Glucose anhydrous	22.7
Sodium chloride	5.38
Calcium chloride dihydrate	0.184
Magnesium chloride hexahydrate	0.051
Sodium hydrogen carbonate	2.10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1.68
Osmolarity	395 mOsm/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 / spike / lineo> connector
<volume> ml x <pack size>

For HomeChoice APD set only available in Denmark, Iceland, Finland, Norway and Sweden:

<Combination package>

<Contains accessories: 1xXXXXXXXX¹ HomeChoice lineset, 1xXXXXXXXX¹ MiniCap and 1xXXXXXXXX¹ Connector protection>

¹Information on product code

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 00116/0412

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 40 Glucose 2,27% w/v / 22,7 mg/ml Clear-Flex

1. NAME OF THE MEDICINAL PRODUCT

PHYSIONEAL 40 Glucose 3,86% w/v / 38,6 mg/ml Clear-Flex
Solution for Peritoneal Dialysis

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Formula after mixing	(g/l)
Glucose monohydrate	42,5
Equivalent to Glucose anhydrous	38,6
Sodium chloride	5,38
Calcium chloride dihydrate	0,184
Magnesium chloride hexahydrate	0,051
Sodium hydrogen carbonate	2,10
Sodium (S)-lactate solution equivalent to sodium (S)-lactate	1,68
Osmolarity	483 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, spike or lineo> connector
<volume> ml x <pack size>

For HomeChoice APD set only available in Denmark, Iceland, Finland, Norway and Sweden:

<Combination package>

<Contains accessories: 1xXXXXXXXX¹ HomeChoice lineset, 1xXXXXXXXX¹ MiniCap and 1xXXXXXXXX¹ Connector protection>

¹Information on product code

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

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12. MARKETING AUTHORISATION NUMBER(S)

PL 00116/0413

13. BATCH NUMBER

Lot{number}

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

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