

### **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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	75,5
Na <sup>+</sup>	132
Ca <sup>++</sup>	1,75
Mg <sup>++</sup>	0,25
Cl <sup>-</sup>	101
HCO <sub>3</sub> <sup>-</sup>	25
C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup>	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 / 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 00116/0408

**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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	126
Na <sup>+</sup>	132
Ca <sup>++</sup>	1,75
Mg <sup>++</sup>	0,25
Cl <sup>-</sup>	101
HCO <sub>3</sub> <sup>-</sup>	25
C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup>	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 / 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 00116/0409

**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**

<b>16. INFORMATION IN BRAILLE</b>
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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 <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	214
Na <sup>+</sup>	132
Ca <sup>++</sup>	1,75
Mg <sup>++</sup>	0,25
Cl <sup>-</sup>	101
HCO <sub>3</sub> <sup>-</sup>	25
C <sub>3</sub> H <sub>5</sub> O <sub>3</sub> <sup>-</sup>	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 / 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 00116/0410

**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**



<b>16. INFORMATION IN BRAILLE</b>
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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 / spike / lineo> 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

**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)
Glucose monohydrate	25.0
Equivalent to Glucose anhydrous	22.7
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	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 / spike / lineo> 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 00116/0409

**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)**

Physioneal 35 Glucose 2,27% w/v / 22,7 mg/ml Clear-Flex

**1. NAME OF THE MEDICINAL PRODUCT**

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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	5,67
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 484 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>

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

**12. MARKETING AUTHORISATION NUMBER(S)**

PL 00116/0410

**13. BATCH NUMBER**

Lot{number}

**14. GENERAL CLASSIFICATION FOR SUPPLY**

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**15. INSTRUCTIONS ON USE**

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

Physioneal 35 Glucose 3,86% w/v / 38,6 mg/ml Clear-Flex