

Public Assessment Report
Glucose 10% w/v solution for infusion
Glucose monohydrate
PL 00116/0406
Baxter Healthcare Ltd

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Lay Summary

The MHRA granted a Marketing Authorisation (licence) to Baxter Healthcare Ltd for the medicinal product Glucose 10% w/v solution for infusion (PL 00116/0406) on 13th April 2007.

Glucose 5% w/v solution has been widely used for years in the treatment of carbohydrate and fluid depletion, and as a vehicle and diluent for injectable preparation of other drugs. Glucose 20% - 50% w/v solution has been widely used as an energy source. The 10% w/v strength products have been similarly licensed for fluid replacement, energy source, and hypoglycaemic coma (including temporary blood volume replacement in haemorrhage and shock).

Scientific Discussion

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Market Authorisations for the medicinal product Glucose 10% w/v solution for infusion (PL 00116/0406) on 13th April 2007.

The application was a stand alone, bibliographical application, under article 10a of EEC Directive 2001/83/EC, as amended, which requires that detailed references to published scientific literature are presented to show that the constituent of the medicinal product has a well established medicinal use, with recognised efficacy and an acceptable level of safety.

Glucose 5% w/v solution has been widely used for years in the treatment of carbohydrate and fluid depletion, and as a vehicle and diluent for injectable preparation of other drugs. Glucose 20% - 50% w/v solution has been widely used as an energy source. The 10% w/v strength products have been similarly licensed for fluid replacement, energy source, and hypoglycaemic coma (including temporary blood volume replacement in haemorrhage and shock).

Glucose 10% w/v Solution for Infusion BP is indicated for:

Supply of carbohydrate during parenteral nutrition.
Prevention and treatment of moderate hypoglycaemia.
Rehydration in case of water loss and dehydration states.
Dilution of compatible medicinal products.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

The specification is in line with the current Ph Eur monograph and the ICH guidelines.

The drug substance manufacturers test batches of the active ingredient according to the methods described in the Ph Eur monograph.

Glucose is stored in appropriate packaging. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided and comply with the proposed specification.

The applicant has provided assurance that the drug substance will be tested for compliance with the pharmacopoeial monograph immediately prior to manufacture of the finished product.

DRUG PRODUCT

The product is a sterile, non-pyrogenic solution for intravenous infusion, packaged in a flexible plastic ‘Viaflo’ bag.

Other Ingredient

The other ingredient is Water for Injections (Ph Eur.).

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out. The results are satisfactory.

Finished product specification

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container

The Viaflo container is composed of non-PVC plastic film, based on polyolefin and polyamide materials, and has good water vapour transmission properties, low leachables profile and exhibits good compatibility with drugs that may be admixed with the infusion. The Viaflo container complies with the Ph Eur monograph 3.2.2.1 “Plastic containers for aqueous solutions for parenteral infusions”

Stability

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 18 months with no specific storage instructions.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY AND ADVICE

A Marketing Authorisation was granted.

PRE-CLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for an application of this type.

MEDICAL ASSESSMENT

This abridged product licence application is for a well-established solution of Glucose 10% presented in a new flexible plastic container comprising non-PVC components (to be known as Viaflo® container).

CLINICAL PHARMACOLOGY

Pharmacodynamic Properties

Glucose 10% w/v Solution for Infusion BP is a hypertonic solution, with an approximate osmolarity of 555 mOsm/l.

The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose is given as a source of carbohydrate in parenteral nutrition. The Glucose 10% w/v solution provides a calorific intake of 400 kcal/l. Furthermore glucose solution for infusion allows hydric supplementation without ionic supplementation.

When medication is added to Glucose 10% w/v Solution for Infusion BP, the overall pharmacodynamics of the solution will depend on the nature of the medicinal product used.

Pharmacokinetic Properties

Two different pathways are involved in the metabolism of glucose: one anaerobic and one aerobic. Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with release of energy.

Efficacy

No new efficacy data are presented. Efficacy is discussed in the Clinical Expert Report.

Safety

No new safety data are presented. Safety is discussed in the Clinical Expert Report.

Clinical Expert Report

A satisfactory clinical expert report was provided from a suitably qualified expert.

Summary of Product Characteristics

The Summary of Product Characteristics is clinically satisfactory.

Package Insert / Patient Information Leaflet

The Patient Information Leaflet is satisfactory.

Labelling

Satisfactory mock ups of the labels were provided.

Discussion

This abridged product licence application is for a well-established solution of Glucose 10% presented in a new flexible plastic container comprising non-PVC components.

As it is not envisaged that the change to the container will affect the efficacy and safety of the product, no new efficacy or safety data have been presented.

Conclusion

A Marketing Authorisation may be granted.

Overall Conclusion and Risk/Benefit Analysis

Quality

The important quality characteristics of Glucose 10% w/v solution for infusion are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

Pre-Clinical

No new preclinical data were submitted and none are required for applications of this type.

Clinical

This abridged product licence application is for a well-established solution of Glucose 10% presented in a new flexible plastic container comprising non-PVC components.

As it is not envisaged that the change to the container will affect the efficacy and safety of the product, no new efficacy or safety data have been presented.

Risk/Benefit Analysis

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk benefit is, therefore, considered to be positive.

Steps Taken During Assessment

1	The MHRA received the application on 03/02/2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 21/02/2005.
3	Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 30/11/2005.
4	The applicant provided further information in regard to the quality assessment on 21/10/2006.
5	The application was determined on 13/04/2007.

Steps Taken after Assessment

None

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glucose 10% w/v Solution for Infusion BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose (as monohydrate): 100.00 g/l

Each ml contains 100 mg glucose (as monohydrate).

For a full list of excipients: see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Clear solution, free from visible particles.

Osmolarity: 555 mOsm/l (approx.)

pH: 3.5 to 6.5

Calorific value: 1680 kJ/l (or 400 kcal/l) (approx.)

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Glucose 10% w/v Solution for Infusion BP is indicated for:

Supply of carbohydrate during parenteral nutrition.

Prevention and treatment of moderate hypoglycaemia.

Rehydration in case of water loss and dehydration states.

Dilution of compatible medicinal products.

4.2 Posology and method of administration

The dosage and rate of administration of Glucose 10% w/v Solution for Infusion BP are determined by several factors including the age, weight, and clinical condition of the patient.

Adults and elderly:

The recommended doses in Table 1 serve as a guideline for an average adult with a body weight of approximately 70 kg.

Table 1.
Guidance on the Dose for Administration to an Adult (70kg)

Indication	Initial daily dose	Rate of administration	Recommended duration of treatment
Supply of carbohydrate during parenteral nutrition	From 500 ml to 3000 ml/day (from 7 to 40 ml/kg/day)	The recommended maximum administration rate should not exceed the patient's glucose oxidation: 5 mg/kg/min (3ml/kg/h)	No limit on duration - dependent on the clinical condition of the patient
Prevention and treatment of moderate hypoglycaemia			
Rehydration in case of water loss and dehydration states			
Dilution of compatible medicinal products	From 50 to 250 ml per dose	Dependent on the nature of the additive	Dependent on the nature of the additive

Babies, Children and Adolescents:

The recommended doses in Table 2 serve as a guideline for babies, children and adolescents, as a function of body weight and age.

Table 2.**Guidance on the Dose for Administration to babies, Children and Adolescents**

Indication	Initial daily dose	Rate of administration	Recommended duration of treatment
Supply of carbohydrate during parenteral nutrition	<ul style="list-style-type: none"> • <u>0-10 kg body weight:</u> 100 ml/kg/day • <u>10-20 kg body weight:</u> 1000 ml+50 ml/kg over 10 kg/day • <u>> 20 kg body weight:</u> 1500 ml+20 ml/kg over 20 kg/day 	<p>The maximum administration rate should not exceed the patient's rate of glucose oxidation:</p> <ul style="list-style-type: none"> • <u>Pre-term and term newborn infant:</u> 6-11 ml/kg/h (10-18 mg/kg/min) • <u>1-3 years:</u> 5-8 ml/kg/h (9-14 mg/kg/min) • <u>4-6 years:</u> 5-7 ml/kg/h (8-11 mg/kg/min) • <u>7-10 years:</u> 4-7 ml/kg/h (7-11 mg/kg/min) • <u>> 11 years:</u> 4 ml/kg/h (7-8.5 mg/kg/min) 	No limit on duration - dependent on the clinical condition of the patient
Prevention and treatment of moderate hypoglycaemia			
Rehydration in case of water loss and dehydration states			
Dilution of compatible medicinal products	From 50 to 100 ml per dose	Dependent on the nature of the additive	Dependent on the nature of the additive

Note:

- Infants and toddlers: age ranges from about 28 days to 23 months (a toddler is an infant who can walk),
- Children and schoolchildren: age ranges from about 2 years to 11 years.

Depending on the patient's clinical condition, a lower flow rate than recommended can be used in order to decrease the risk of undesirable osmotic diuresis.

When the solution is used for dilution or delivery of compatible therapeutic additives for administration intravenously, the directions for use of the

additive therapeutic substances will dictate the appropriate volumes for each therapy.

Administration:

Administration is usually via a peripheral or central vein.

Monitoring:

Treatment should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular plasma-glucose concentration, fluid balance and plasma electrolytes, should be monitored on regular basis and during treatment.

4.3 Contraindications

The solution is contra-indicated in patients presenting with:

- Uncompensated diabetes,
- Hyperosmolar coma,
- Haemodilution and extracellular hyperhydration or hypervolaemia,
- Hyperglycaemia and hyperlactataemia,
- Severe renal insufficiency (with oliguria / anuria),
- Uncompensated cardiac failure,
- General oedema and ascitic cirrhosis.

The contra-indications related to any medicinal product that is added to the glucose solution should be considered.

4.4 Special warnings and precautions for use

Glucose 10% w/v Solution for Infusion BP is a hypertonic solution with an approximate osmolarity of 555 mOsm/l.

High volume infusion must be performed with specific monitoring in patients with cardiac, pulmonary or renal failure.

As glucose tolerance may be impaired in patients with diabetes, renal failure or acute critical illness, clinical and biological parameters, in particular plasma-electrolytes and glycaemia should be particularly closely monitored. If hyperglycaemia occurs, the rate of infusion should be adjusted or insulin should be administered.

In case of prolonged administration or high glucose dose, care should be taken to avoid hypokalaemia by monitoring plasma potassium levels and administering a potassium supplement as appropriate.

The infusion of solutions containing glucose is contraindicated in the first 24 hours following head trauma and blood glucose concentration should be closely monitored during intracranial hypertension episodes.

Administration of glucose containing solutions may lead to hyperglycaemia. Therefore, it is recommended not to use glucose solution after acute ischaemic stroke as hyperglycaemia has been implicated in increasing cerebral ischaemic brain damage and impairing recovery.

Glucose solution should not be administered through the same equipment as whole blood, as haemolysis and clumping can occur.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Glucose 10% Solution for Infusion BP can be used safely during pregnancy and lactation as long as the electrolyte and fluid balance are controlled and are within the physiologic ranges.

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The administration of Glucose 10% w/v Solution for Infusion BP can lead to the development of:

- Hyperglycaemia,
- Fluid-balance disturbances (hypervolaemia),
- Electrolyte disturbances (hypokalaemia, hypomagnesaemia, and hypophosphataemia).

-

Adverse reactions may be associated with the route of administration including febrile response, fever, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Adverse reactions may be associated with the medicinal product added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects.

In case of undesirable effect(s), the infusion must be discontinued.

Table 3.
Frequencies

Frequency	System Organ Class	Symptoms (LLT terms MedDRA 6.1)
Common (>1/100 - < 1/10)	Metabolism and nutrition disorders	Electrolyte disturbance and hyperglycaemia
Uncommon (>1/1000 - < 1/100)	Metabolism and nutrition disorders	Hemodilution & Hypervolaemia
	Investigations	Glycosuria
	General disorders and administration site conditions	Shivering
	Skin and subcutaneous tissue disorders	Sweating
	General disorders and administration site conditions	Febrile reaction
	General disorders and administration site conditions	Fever
	General disorders and administration site conditions	Infection at site of injection
Rare (>1/10,000 - <1/1,000)	General disorders and administration site conditions	Thrombophlebitis
	Immune system disorders	Allergic reaction (additive drugs)

4.9 Overdose

Prolonged administration of Glucose 10% w/v Solution for Infusion BP may cause hyperglycaemia, hyperosmolarity, glycosuria, osmotic diuresis and dehydration. Rapid infusion may create a fluid inflation with haemodilution and hypervolaemia and, when the oxidation capacity of glucose is exceeded, it may cause hyperglycaemia. Decrease in serum potassium and inorganic phosphate may also occur.

When Glucose 10% w/v Solution for Infusion BP is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over-infusion will be related to the nature of the additives being used.

In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group “Carbohydrates”, ATC code: B05BA03.

Glucose 10% w/v Solution for Infusion BP is a hypertonic solution, with an approximate osmolarity of 555 mOsm/l.

The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose is given

as a source of carbohydrate in parenteral nutrition. The Glucose 10% w/v solution provides a caloric intake of 400 kcal/l. Furthermore glucose solution for infusion allows hydric supplementation without ionic supplementation. When medication is added to Glucose 10% w/v Solution for Infusion BP, the overall pharmacodynamics of the solution will depend on the nature of the medicinal product used.

5.2 Pharmacokinetic properties

Two different pathways are involved in the metabolism of glucose: one anaerobic and one aerobic.

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with release of energy.

When medication is added to Glucose 10% w/v Solution for Infusion BP, the overall pharmacokinetics of the solution will depend on the nature of the medicinal product used.

5.3 Preclinical safety data

Preclinical safety data of this solution for infusion are not relevant since its constituents are physiological components of animal and human plasma.

The safety of potential additives should be considered separately.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

Glucose solution should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and clumping can occur.

Incompatibility of the medicinal product to be added with the solution in Viaflo container must be assessed before its addition.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

The instructions for use of the medicinal product to be added must be consulted.

Before adding a drug, verify if it is soluble and stable in water at the pH range of the Glucose 10% w/v Solution for Infusion BP (pH 3.5 to 6.5).

When a compatible medication is added to the Glucose Intravenous Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

6.3 Shelf life

Unopened:

- 250 ml bags: 18 months
- 500 ml bags: 18 months
- 1000 ml bags: 18 months

In-use shelf life: From a microbiological point of view, the diluted product must be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

The bags known as Viaflo are composed of polyolefin/polyamide co-extruded plastic (PL 2442).

The bags are overwrapped with a protective plastic pouch composed of polyamide/ polypropylene.

Bag sizes: 250 ml, 500 ml and 1000 ml

Not all pack sizes may be marketed.

Outer carton contents:

- 30 bags of 250 ml
- 20 bags of 500 ml
- 10 bags of 1000 ml

6.6 Special precautions for disposal

The solution for infusion should be visually inspected before use.

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

Do not use plastic containers connected in series. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the appropriate port. When an additive is used, verify its isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

1. Opening

Remove the Viaflo container from the overpouch just before use.

Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be compromised.

Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution

2. Preparation for administration

Use sterile material for preparation and administration.

- a. Suspend container from eyelet support.
- b. Remove plastic protector from outlet port at bottom of container:
- c. Grip the small wing on the neck of the port with one hand.
- d. Grip the large wing on the cap with the other hand and twist.
- e. The cap will pop off.
- f. Use an aseptic method to set up the infusion.
- g. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible.

To add medication before administration

- a. Disinfect medication site.
- b. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture resealable medication port and inject.
- c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.
- d. Caution: Do not store bags containing added medications.

To add medication during administration

- a. Close clamp on the set.
- b. Disinfect medication site.
- c. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture resealable medication port and inject.
- d. Remove container from IV pole and/or turn to an upright position.
- e. Evacuate both ports by tapping gently while the container is in an upright position.
- f. Mix solution and medication thoroughly.
- g. Return container to in use position, re-open the clamp and continue administration.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL00116/0406

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

13/04/2007

10 DATE OF REVISION OF THE TEXT

13/04/2007

Labels and Leaflet



**Glucose 10% w/v Solution for Infusion BP
in VIAFLO containers**

Patient Information Leaflet

Please read this leaflet carefully

- It contains a summary of information on Glucose 10% w/v Solution for Infusion BP.
- If you are unsure about anything please ask the doctor, pharmacist or nursing staff.

MARKETING AUTHORISATION HOLDER
The company responsible for the product (Marketing Authorisation Holder) is:

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

MANUFACTURERS
Glucose 10% w/v Solution for Infusion BP is made at:

Bieffe Medital Sabiñánigo
Ctra de Biescas, Senegüé,
22666 Sabiñánigo (Huesca)
Spain

1. WHAT IS GLUCOSE 10% W/V SOLUTION FOR INFUSION BP?

It is an hypertonic solution for infusion. Each 1000 ml of solution contains 100 g Glucose (as monohydrate) in Water for injections which provides 1680 kJ/l (or 400 kcal/l) approximately.

The solution is for intravenous administration and may be presented in either 250 ml, 500 ml or 1000 ml polyolefin/polyamide plastic containers protected by a plastic overwrap. Each unit is one dose. For use under medical supervision.

2. WHAT IS IT USED FOR?

Glucose 10% w/v Solution for Infusion BP may be used to provide a source of carbohydrate (glucose) when administration of glucose by mouth is not possible or enough. This solution may be used as a source of glucose if you have a low level of glucose in your blood (hypoglycaemia). It may also be used to replace the volume of fluid lost as a result of a variety of medical conditions or as the liquid in which other drugs are dissolved before they are administered to you. Your doctor may also decide to use this medicine for other reasons.

3. BEFORE YOU RECEIVE GLUCOSE 10% W/V SOLUTION FOR INFUSION BP:

Are there times when it should not be used?

The solution is safe to use in most patients but you will not be given this medicine if:

- your blood already contains abnormally high levels of glucose (uncompensated diabetes, hyperosmolar coma) or lactic acid, or abnormally low levels of potassium or sodium salts (haemodilution and hypervolemia).
- you have renal failure (possibly indicated by a reduction in urine excretion).
- you have uncompensated cardiac failure.
- you have accumulation of water in tissues (general oedema).

Are there situations where it should be administered with special care?

If you are a diabetic or have a problem that affects your heart, lungs, kidneys, liver, or the quantity of ions in your plasma, you will probably require extra tests to establish your suitability to receive this medicine.

If you have had a head trauma, a stroke or have recently undergone an operation on your brain, or if there is known bleeding in your brain or spinal region (intracranial hypertension) then your doctor may not give you this solution.

Pregnancy, Breast feeding:

There is no restriction on use in the case of pregnancy or breast feeding. Electrolytes and fluid balance should be controlled.

Please tell your doctor if you are pregnant or breast feeding.

Effect on the ability to drive or to use machines?

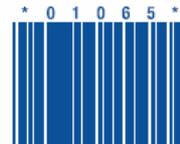
Not relevant.

Can I be given other medicines at the same time?

Certain drugs are known to modify the normal response expected from Glucose 10% w/v Solution for Infusion BP or they themselves can have their effect changed by the solution and should not be used together as they clinically interact with each other.

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If you are taking one of these drugs your doctor will probably not give you this solution. Glucose 10% w/v Solution for Infusion BP should not be infused through the same equipment as a blood transfusion (risk of blood clotting and haemolysis). Please inform your doctor if you are taking or have recently taken any other medicines, including any not prescribed.

4. HOW GLUCOSE 10% W/V SOLUTION FOR INFUSION BP WILL BE GIVEN TO YOU:

How much and how often?

Your doctor will decide how much you need and when it will be given to you. This will depend upon your age, weight, clinical and biological conditions (in particular your hydration state) as well as the treatment purpose and the nature of any drug given simultaneously.

How will the solution be administered?

Glucose 10% w/v Solution for Infusion BP will be given to you through a plastic tube into your vein using sterile equipment and aseptic technique. Your doctor may decide to give you the medicine in a different way.

During long-term infusion, the doctor can decide to give you an appropriate nutritive supply.

If you receive more Glucose 10% w/v Solution for Infusion BP than you should?

Prolonged administration may lead to a high glucose concentration in the blood (hyperglycaemia), a high blood concentration (hyperosmolarity of the blood), glucose in the urine (glycosuria), a large volume of urine (osmotic diuresis) and dehydration. Decrease of potassium and inorganic phosphate in your blood may also occur.

Rapid infusion may lead to fluid overload with dilution of your blood and an increase in the volume of blood (hypervolemia) and may also result in an elevated level of glucose in the blood (hyperglycaemia).

If you notice any change in the way you feel after or during receiving the medicine you should tell your doctor or nurse straight away. The infusion should be stopped. Your doctor will take the appropriate measures.

If a medication is added to the solution infused, the signs and any symptoms of over infusion will be related to the nature of the additive being used.

5. POSSIBLE SIDE EFFECTS

Elevated levels of glucose in your blood may occur (hyperglycaemia).

Disturbances of the electrolyte concentrations in the blood are possible.

An increased blood volume (haemodilution and hypervolemia) and accumulation of liquids in tissues may occur.

Glucose in the urine may occur (glycosuria).

Like all infusions, Glucose 10% w/v Solution for Infusion BP may also cause side effects including shivering, sweating, febrile reaction, fever, allergic reaction or infection at the site of injection (redness, swelling, irritation or venous phlebitis around the area where the medicine enters your body).

You should tell your doctor or nurse immediately if you notice any of the possible side effects listed. Your doctor will take the appropriate measures and could decide to discontinue the infusion.

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

6. STORING AND USING GLUCOSE 10% W/V SOLUTION FOR INFUSION BP

This medicinal product does not require any special precautions for storage. Glucose 10% w/v Solution for Infusion BP should be kept out of the reach and sight of children.

Each unit of Glucose 10% w/v Solution for Infusion BP has an expiry date printed on the label. You will not be given the medicine if this date has passed or if the solution is not clear, contains visible particles, or if the unit is damaged in any way.

The unit will not be removed from the overwrap until ready for use.

The inner bag maintains the sterility of the product.

Any unused portion of the unit will be discarded.

Partially used bags will not be reconnected.

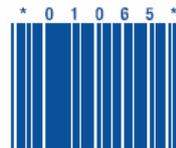
This leaflet was revised in February 2007

VIAFLO is a trademark of Baxter International Inc.



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SA-30-01-065



Baxter

FE0164



1000 ml

100

100

200

Glucose 10% w/v

200

Glucose 10% w/v Solution for Infusion BP

300 Solution for infusion (Viaflo container) **Hypertonic** **300**
 Single Dose pH 3.5 – 6.5

Sterile, free from bacterial endotoxins

400 Osmolarity 555 mOsm/l (approx) **400**

Calorific value 400 kcals/l (approx)

Formula per 1000 ml

500 Glucose (as monohydrate) **110.0 g** **500**

Water for injections

For intravenous administration

600 Keep out of reach and sight of children **600**

Read the package leaflet before use

Do not administer simultaneously with blood

Do not use unless solution is clear without visible particles and container undamaged

700 **700**

Check additive compatibility with both the solution and container prior to use

800 Thorough and careful aseptic mixing of any additive is mandatory **800**

Do not remove from overwrap until ready for use

Discard any unused portion after first use

Do not reconnect partially used bags

For use under medical supervision

900

900

POM



PL00116/0406

UN-35-01-108

Baxter Healthcare Ltd
 Thetford Norfolk
 IP24 3SE
 United Kingdom



5 413760 226262

Lot

EXP

Baxter



FE0162

250 ml

Glucose 10% w/v

Glucose 10% w/v Solution for Infusion BP

50 Solution for infusion (Viaflo container) **Hypertonic** **50**
50 Single Dose **pH 3.5 – 6.5**

Sterile, free from bacterial endotoxins
 Osmolarity 555 mOsm/l (approx)
 Calorific value 400 kcals/l (approx)

100 Formula per 250 ml **100**
100 Glucose (as monohydrate) 27.5 g

Water for injections

For intravenous administration

150 Keep out of reach and sight of children Read the package leaflet **150**
150 before use Do not administer simultaneously with blood Do not
 use unless solution is clear without visible particles and container
 undamaged Check additive compatibility with both the solution and
 container prior to use Thorough and careful aseptic mixing of any
 additive is mandatory Do not remove from overwrap until ready for
 use Discard any unused portion after first use Do not reconnect
 partially used bags For use under medical supervision

PL00116/0406

Baxter Healthcare Ltd
 Thetford Norfolk
 IP24 3SE
 United Kingdom

200



5



413760 239859

UN-35-01-110

200

Lot

EXP

Baxter



FE0163

500 ml

Glucose 10% w/v

Glucose 10% w/v Solution for Infusion BP

Solution for infusion (Viaflo container) Hypertonic
 Single Dose pH 3.5 – 6.5
 Sterile, free from bacterial endotoxins

50	Osmolarity 555 mOsm/l (approx) Calorific value 400 kcals/l (approx)	50
100	Formula per 500 ml Glucose (as monohydrate) 55.0 g	100
150	Water for injections	150
	For intravenous administration	
200	Keep out of reach and sight of children Read the package leaflet before use	200
250	Do not administer simultaneously with blood Do not use unless solution is clear without visible particles and container undamaged	250
300	Check additive compatibility with both the solution and container prior to use Thorough and careful aseptic mixing of any additive is mandatory	300
350	Do not remove from overwrap until ready for use Discard any unused portion after first use Do not reconnect partially used bags For use under medical supervision	350

400	 	400
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450	PL00116/0406 Baxter Healthcare Ltd Thetford Norfolk IP24 3SE United Kingdom	UN-35-01-109	450
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Lot

EXP

**FE0164 10 x 1000 ml
Glucose 10% w/v
Solution for infusion BP**

Viallo Containers (\approx 11.5 Kg)

Solution for infusion
Sterile, free from bacterial endotoxins
Osmolarity 555 mOsm/l (approx)
Calorific value 400 kcal/l (approx)

Hypertonic
pH 3.5 - 6.5
Single Dose

Formula per 1000 ml
Glucose (as monohydrate) 110.0 g
Water for injections



For intravenous administration. Keep out of reach and sight of children. Read the package leaflet before use. Do not administer simultaneously with blood. Do not use unless solution is clear without visible particles and container undamaged. Check additive compatibility with both the solution and container prior to use. Thorough and careful aseptic mixing of any additive is mandatory. Do not remove from overwrap until ready for use. Discard any unused portion after first use. Do not reconnect partially used bags. For use under medical supervision.

PL00116/0406
POM

LOT: XXXXXXXX
EXP: XXXXXXXX



(01)55413760226267(17)XXXXXX(10)XXXXXXXXXX

**FE0164
Glucose 10% w/v
Solution for infusion BP**

10 x 1000 ml

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Thetford Norfolk
IP24 3SE
United Kingdom

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**LOT:
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EXP:
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P000E527 XX - 0001

**FE0163 20 x 500 ml
Glucose 10% w/v
Solution for infusion BP**

Viallo Containers (\approx 12 Kg)

Solution for infusion
Sterile, free from bacterial endotoxins
Osmolarity 555 mOsm/l (approx)
Calorific value 400 kcal/l (approx)

Hypertonic
pH 3.5 - 6.5
Single Dose

Formula per 500 ml
Glucose (as monohydrate) 55.0 g
Water for injections



For intravenous administration. Keep out of reach and sight of children. Read the package leaflet before use. Do not administer simultaneously with blood. Do not use unless solution is clear without visible particles and container undamaged. Check additive compatibility with both the solution and container prior to use. Thorough and careful aseptic mixing of any additive is mandatory. Do not remove from overwrap until ready for use. Discard any unused portion after first use. Do not reconnect partially used bags. For use under medical supervision.

PL00116/0406
POM

LOT: XXXXXXXX
EXP: XXXXXXXX



(01)55413760226250(17)XXXXXX(10)XXXXXXXXXX

**FE0163
Glucose 10% w/v
Solution for infusion BP**

20 x 500 ml

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**LOT:
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EXP:
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P000E528 XX - 0001

**FE0162 30 x 250 ml
Glucose 10% w/v**

Solution for infusion BP

Viaflo Containers

(≈ 9.5 Kg)

Solution for infusion
Sterile, free from bacterial endotoxins
Osmolarity 555 mOsm/l (approx)
Calorific value 400 kcals/l (approx)

Hypertonic
pH 3.5 - 6.5
Single Dose



Formula per 250 ml

Glucose (as monohydrate) 27.5 g
Water for injections

For intravenous administration. Keep out of reach and sight of children. Read the package leaflet before use. Do not administer simultaneously with blood. Do not use unless solution is clear without visible particles and container undamaged. Check additive compatibility with both the solution and container prior to use. Thorough and careful aseptic mixing of any additive is mandatory. Do not remove from overwrap until ready for use. Discard any unused portion after first use. Do not reconnect partially used bags. For use under medical supervision.

PL00116/0406

POM

LOT: XXXXXXXX

EXP: XXXXXXXX



(01)55413760239854(17)XXXX00(10)XXXXXXXXXX

**FE0162
Glucose 10% w/v
Solution for infusion BP**

30 x 250 ml

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IP24 3SE
United Kingdom

PL00116/0406



**LOT:
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EXP:
XXXXXXXXXX**

P000E529 XX - 0001