SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CLINIMIX N12G20, solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

CLINIMIX N12G20 is packaged in a dual compartment plastic bag containing respectively an amino acid solution without electrolytes and a glucose solution without calcium.

The injectable amino acid solution contains 15 L-amino acids (8 essential amino acids) needed for the protein synthesis.

The amino acid profile is the following:
- Essential amino acids/Total amino acids = 41.3 %
- Essential amino acids/Total nitrogen = 2.83
- Branched chain amino acids/Total amino acids = 19 %

The quantitative composition of CLINIMIX N12G20 is the following:

	7% Amino acid solution without electrolytes	**20% Glucose solution without calcium**
Active ingredients		
L-Leucine	5.11 g/l	
L-Phenylalanine	3.92 g/l	
L-Methionine	2.80 g/l	
L-Lysine (as L-Lysine hydrochloride)	4.06 g/l (5.07 g/l)	
L-Isoleucine	4.20 g/l	
L-Valine	4.06 g/l	
L-Histidine	3.36 g/l	
L-Threonine	2.94 g/l	
L-Tryptophan	1.26 g/l	
L-Alanine	14.49 g/l	
L-Arginine	8.05 g/l	
Glycine	7.21 g/l	
L-Proline	4.76 g/l	
L-Serine	3.50 g/l	
L-Tyrosine	0.28 g/l	
Glucose (as monohydrate glucose)		200 g/l (220 g/l)

For the full list of excipients, see section 6.1

After mixing of the contents of both compartments, the composition of the binary mixture, for all the available bag sizes, is the following:

	N12G20 1 l	**N12G20 1.5 l**	**N12G20 2 l**
Nitrogen (g)	5.8	8.7	11.6
Amino acids (g)	35	53	70
Glucose (g)	100	150	200
Total calories (kcal)	540	810	1080
Glucose calories (kcal)	400	600	800
Acetate (mmol)	27	41	54
Chloride (mmol)	15	22	29
pH	6		
Osmolarity (mOsm/l)	920		

3 PHARMACEUTICAL FORM

Solution for infusion.

- Appearance prior to mixing of compartments: The aminoacid and glucose solutions are clear and colourless or slightly yellow

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Parenteral nutrition when oral or enteral alimentation is impossible, insufficient or contraindicated.

For patient undergoing long-term parenteral nutrition, the addition of a lipid emulsion to CLINIMIX in order to supply both calories and essential fatty acids is possible.

4.2 Posology and method of administration

Posology

The dosage should be individualised based on the patient's nutritional/fluid requirements, energy expenditure, clinical status, body weight, and the ability to metabolise constituents of CLINIMIX, as well as additional energy or proteins given orally/enterally.
In adults, the requirements range from 0.16 g of nitrogen/kg/d (approximately 1 g of amino acid/kg/d) to 0.32 g of nitrogen/kg/d (approximately 2 g of amino acid/kg/d).

In infants, the requirements range from 0.16 g of nitrogen/kg/d (approximately 1.0 g of amino acid/kg/d) to 0.40 g of nitrogen/kg/d (approximately 2.5 g of amino acid/kg/d).

In adults and patients 12 to 18 year of age, calorie requirements range from 25 kcal/kg/d to 40 kcal/kg/d, depending on the nutritional status of the patient and the degree of catabolism. Patients less than 12 years of age may have higher requirements.

The maximum daily doses of each constituent of CLINIMIX N12G20 (i.e., amino acids and glucose) should be based on individual total nutritional requirements and patient tolerance.

The maximum infusion rate is 2.5 ml/kg/hour or 150 ml/hour to 175 ml /hour (for a patient weighing 60 kg to 70 kg). The maximum daily dose is 40 ml/kg e.g. 2400 ml to 2800 ml (for a patient weighing 60 kg to 70 kg).

Paediatric population
The dosage should be individualised based on the patient's nutritional/fluid requirements, energy expenditure, clinical status, body weight, and the ability to metabolise constituents of CLINIMIX, as well as additional energy or proteins given orally/enterally. In addition, daily fluid, nitrogen, and energy requirements continuously decrease with age.

Clinical situations may exist where patients require amounts of nutrients varying from the composition of CLINIMIX. In this situation any volume (dose) adjustments must take into consideration the resultant effect this will have on the dosing of all other nutrient components of CLINIMIX. The infusion rate and volume should be determined by the consulting physician experienced in paediatric parenteral nutrition and intravenous fluid therapy.

This product does not contain the amino acids cysteine and taurine, considered conditionally essential for neonates and infants.

This medicinal product is not recommended for preterm, and term neonates and for children below 2 years of age.

For children 2 years old and above cysteine and taurine should be administered, if deemed needed, by the consulting physician experienced in paediatric parenteral nutrition and intravenous fluid therapy.

Recommended CLINIMIX N12G20 Dosing per Age Group

Age	Patients 2 to 3 years		Patients 3 to 11 years		Patients 12 to 18 years	
	Recommended Dosing[1]	Maximum Recommended Dose	Recommended Dosing[1]	Maximum Recommended Dose	Recommended Dosing[1]	Maximum Recommended Dose
Infusion Rate (mL/kg/hr)		3.0		2.4		2.4
Fluid (mL/kg/day)	80-100	71.4	60-100	57.1	50-80	57.1
Amino Acid (g/kg/d) (Nitrogen (g/kg/d))	1.0-2.5 (0.16-0.4)	2.5 (0.40)	1.0-2.0 (0.16-0.32)	2.0 (0.32)	1.0-2.0 (0.16-0.32)	2.0 (0.32)
Glucose (g/kg/d)	2.2-8.6	7.1	1.4-8.6	5.7	0.7-5.8	5.7
Rate Limiting Component		Amino acids		Amino acids		Amino acids

[1]Maximum Recommended values from 2018 ESPGHAN/ESPEN Guidelines

Method of administration

For single use only.

It is recommended that after opening the bag, the contents should be used immediately, and should not be stored for a subsequent infusion.

Administer the product only after breaking the seal and mixing the contents of both compartments. Appearance of the solution after mixing: clear and colourless or slightly yellow solution. For instructions for preparation and handling of the solution see section 6.6.

The osmolarity of a specific infusion solution must be taken into account when peripheral administration is considered. Solutions or mixtures with an osmolarity above 800 mOsm/l should be infused via a central vein (also see section 4.4).

As indicated on an individual basis, vitamins and trace elements and other components (including lipids) can be added to the regimen to prevent deficiencies and complications from developing (see section 6.2).

The flow rate should be increased gradually during the first hour.

The rate of administration should be adjusted according to the dosage, the characteristics of the infused solution, the total volume intake per 24 hours and the duration of the infusion. The infusion time should be higher than 8 hours.

To reduce the risk of hypoglycaemia after discontinuation, a gradual decrease in flow rate in the last hour of administration should be considered.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 4.4, 6.3 and 6.6).

4.3 Contraindications

- Known hypersensitivity to any of the active substances or excipients listed in section 6.1, or to the components of the container.
- Amino acid metabolism disorders
- Severe hyperglycaemia
- Metabolic acidosis, hyperlactataemia

4.4 Special warnings and precautions for use

WARNINGS

Hypersensitivity/infusion reactions including hypotension, hypertension, peripheral cyanosis, tachycardia, dyspnoea, vomiting, nausea, urticaria, rash, pruritus, erythema, hyperhidrosis, pyrexia, and chills have been reported with CLINIMIX formulations.

Anaphylaxis has been reported with other parenteral nutrition products.

Special clinical monitoring is required at the beginning of any intravenous infusion. Should any abnormal sign or symptom occur, e.g. for hypersensitivity or infusion reaction, the infusion must be stopped immediately.

Solutions containing glucose should be used with caution, if at all, in patients with known allergy to corn or corn products.

Pulmonary vascular precipitates have been reported in patients receiving parenteral nutrition. In some cases, fatal outcomes have occurred. Excessive addition of calcium and phosphate increases the risk of the formation of calcium phosphate precipitates. Precipitates have been reported even in the absence of phosphate salt in the solution. Precipitation distal to the in-line filter and suspected in vivo precipitate formation have also been reported.

If signs of pulmonary distress occur, the infusion should be stopped and medical evaluation initiated.

In addition to inspection of the solution, the infusion set and catheter should also periodically be checked for precipitates.

Infection and sepsis may occur as a result of the use of intravenous catheters to administer parenteral formulations, poor maintenance of catheters or contaminated solutions. Immunosuppression and other factors such as hyperglycaemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycaemia can help recognize early infections.

The occurrence of septic complications can be decreased with heightened emphasis on aseptic technique in catheter placement, maintenance, as well as aseptic technique in nutritional formula preparation.

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Hypertonic solutions may cause venous irritation if infused into a peripheral vein. The choice of a peripheral or central vein depends on the final osmolarity of the mixture.

The general accepted limit for peripheral infusion is about 800 mOsm/l but it varies considerably with the age and the general condition of the patient and the characteristics of the peripheral veins.

Do not connect bags in series in order to avoid air embolism due to possible residual air contained in the primary bag.

PRECAUTIONS

Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion.

Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs.

Frequent clinical evaluation and laboratory determinations are necessary for correct monitoring during administration. These should include ionogram and kidney and liver function tests.

The electrolyte requirements of patients receiving the solutions should be carefully determined and monitored especially for the electrolyte-free solutions. CLINIMIX without electrolytes should not be used in cases of hypokalaemia and hyponatremia.

Glucose intolerance is a common metabolic complication in severely stressed patients. With the infusion of the products, hyperglycaemia, glycosuria, and hyperosmolar syndrome may occur. Blood and urine glucose should be monitored on a routine basis and for diabetics insulin dosage should be adapted, if necessary.

Use with caution in patients with renal insufficiency, particularly if hyperkalaemia is present, because of the risk of developing or worsening metabolic acidosis and hyperazotemia if extra-renal waste removal is not being performed. Fluid and electrolyte status should be closely monitored in these patients. In case of severe kidney failure, specially formulated amino acid solutions should be preferred.

Caution should be exercised in administering CLINIMIX to patients with adrenal insufficiency.

Care should be taken to avoid circulatory overload particularly in patients with pulmonary oedema, cardiac insufficiency and/or failure. Fluid status should be closely monitored.

In patients with pre-existing liver disease or hepatic insufficiency, apart from routine liver function tests, possible symptoms of hyperammonaemia should be controlled.

Hepatobiliary disorders including cholestasis, hepatic steatosis, fibrosis and cirrhosis, possibly leading to hepatic failure, as well as cholecystitis and cholelithiasis are known to develop in some patients on parenteral nutrition. The aetiology of these disorders is thought to be multifactorial and may differ between patients. Patients developing abnormal laboratory parameters or other signs of hepatobiliary disorders should be assessed early by a clinician knowledgeable in liver diseases in order to identify possible causative and contributory factors, and possible therapeutic and prophylactic interventions.

Increase in blood ammonia levels and hyperammonemia may occur in patients receiving amino acid solutions. In some patients this may indicate the presence of a congenital disorder of amino acid metabolism (see section 4.3) or hepatic insufficiency.

Blood ammonia should be measured frequently in newborns and infants to detect hyperammonemia, which may indicate the presence of a congenital abnormality of amino acid metabolism.

Depending on extent and aetiology, hyperammonemia may require immediate intervention.

A too rapid infusion of amino acids may result in nausea, vomiting and chills. In such cases, discontinue the infusion immediately.

In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

Paediatric population

This medicinal product is not recommended for preterm, and term neonates and for children below 2 years of age.

- There have been no studies performed in the paediatric population.
- See above regarding monitoring for hyperammonemia in paediatric patients.

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with trace elements and/or vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products.

When used in neonates and children below 2 years, CLINIMIX should be protected from ambient light until administration is completed (see sections 4.2, 6.3 and 6.6).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of CLINIMIX in fertility, pregnancy and lactation has not been proven due to the lack of clinical studies. The prescriber should consider the benefit/risk relationship in order to administer CLINIMIX to pregnant or breast-feeding women.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Potential undesirable effects may occur as a result of inappropriate use: for example, overdose or excessively fast infusion rate (see sections 4.4 and 4.9).

Post-marketing Adverse Reactions

The following adverse reactions have been reported with CLINIMIX formulations in the post-marketing experience, listed by MedDRA System Organ Class (SOC) and by Preferred Term

System Organ Class (SOC)	Preferred MedDRA Term	Frequency[a]
Immune system disorders	Hypersensitivity*	Not known

a: Frequency is defined as very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100): rare (≥ 1/10,000 to < 1/1000); very rare (< 1/10,000); and not known (cannot be estimated from the available data).

*Includes the following manifestations: Hypotension, Hypertension, Peripheral cyanosis, Tachycardia, Dyspnoea, Vomiting, Nausea, Urticaria, Rash, Pruritus, Erythema, Hyperhidrosis, Pyrexia, Chills

Class Reactions

Other adverse reactions reported with parenteral nutrition include:
•Anaphylaxis
•Pulmonary vascular precipitates
•Hyperglycaemia; Hyperammonemia, Azotemia
•Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased
•Cholecystitis, Cholelithiasis

•Infusion site thrombophlebitis, Venous irritation (Infusion site phlebitis, Pain, Erythema, Warmth, Swelling, Induration)
Glucose intolerance is a common metabolic complication in severely stressed patients. With the infusion of the products, hyperglycaemia, glycosuria, and hyperosmolar syndrome may occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

In the event of inappropriate administration (overdose, and/or infusion rate higher than recommended), hypervolemia, electrolyte disturbances or acidosis may occur and result in severe or fatal consequences. In such situations, the infusion must be stopped immediately. If medically appropriate, further intervention may be indicated.

Hyperglycaemia, glycosuria, and a hyperosmolar syndrome may occur with excessive glucose infusion.

A too rapid infusion of amino acid may result in nausea, vomiting and chills. In such cases, discontinue the infusion immediately (see section 4.4).

In some serious cases, haemodialysis, haemofiltration, or haemo-dia-filtration may be necessary.

There is no specific antidote for overdose. Emergency procedures should include appropriate corrective measures, with particular attention to respiratory and cardiovascular systems.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parental nutrition / mixtures ATC code: B05 BA 10.

As a parenteral nutrition intravenous fluid, CLINIMIX, solution for infusion provides nutritional support to maintain the complex nitrogen-energy balance which may be altered by nutritional depletion and trauma. CLINIMIX solutions provide a biologically available source of nitrogen (L-amino acids), carbohydrates (as glucose) and electrolytes.

5.2 Pharmacokinetic properties

The amino acids, electrolytes and glucose of CLINIMIX are distributed, metabolised and excreted in an identical manner typical to the separate amino acids, glucose and electrolytes intravenous solutions.

5.3 Preclinical safety data

No preclinical studies with CLINIMIX have been performed.

Preclinical studies performed using the solutions of amino acids and glucose contained in CLINIMIX of different qualitative compositions and concentrations have not, however, revealed any specific toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Amino acids solution: Acetic acid (for pH adjustment)
Water for injections

Glucose solution: Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

Additives may be incompatible, refer to the manufacturer for further details. If additives are necessary, compatibilities should be checked and the stability of mixtures should be controlled.
The solution should not be administered with, before, or after an administration of blood through the same equipment because of the possibility of pseudoagglutination.
As with any parenteral nutrition admixture, calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium phosphate precipitates.

6.3 Shelf life

- For the dual bags in their overpouch, the shelf life is 2 years.

- After the peel seal activation, chemical and physical in-use stability has been demonstrated for 7 days at 2 to 8°C followed by 48 hours below 25°C.

- When additions have been made, from a microbiological point of view, the admixture should 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 additions have been made under controlled and validated aseptic conditions. If longer storage periods are required in exceptional circumstances, the company can be contacted as chemical and physical in-use stability data for 7 days at 2-8°C followed by 48 hours below 25°C are available for the products listed in section 6.6.c.

- When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see sections 4.2, 4.4 and 6.6)

6.4 Special precautions for storage

Do not freeze.
For storage conditions of the medicinal product, see section 6.3.
Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

CLINIMIX without electrolytes is packaged in a dual compartment plastic bag containing respectively an amino acid solution without electrolytes and a glucose solution without calcium.

The dual container is a multilayer plastic bag made of following material (from outer to inner): PCCE/EVA and Maleic acid/EVA/PE-PP copo and SEBS packaged in an oxygen barrier overpouch. The overpouch consists of clear plastic laminate and contains an oxygen-absorbing sachet. The sachet must be discarded after removal of the overpouch. The multilayer plastic is compatible with lipids.

Both compartments are separated by a peel seal (see Figure 1). Just before administration, the contents of both chambers are mixed by squeezing or rolling the compartments to break the seal.

3 different formats are available:

1 litre	Package size: 8 1 bag of 1 litre
1.5 litres	Package size: 6 1 bag of 1.5 litres
2 litres	Package size: 4 1 bag of 2 litres

The compartments volumes are the following:

	Bag size		
Compartments	1l	1.5l	2l
Amino acid solution	500 ml	750 ml	1000 ml
Glucose solution	500 ml	750 ml	1000 ml

Not all pack sizes may be marketed

6.6 Special precautions for disposal

Warning: Administer the product only after breaking the seal and mixing the contents of both compartments.

CLINIMIX activation can be performed in the overpouch or after its removal.

a. To open the overpouch

- Use the slits at each side to tear overwrap.
- Do not use unless the solution is clear, colourless or slightly yellow and the container undamaged.

b. To mix solutions

- Ensure that the product is at room temperature.
- Grasp the container firmly on each side of the top of the bag.
- Squeeze or roll to activate (see Figure 2).
- Mix by inverting the bag 2 or 3 times.
- Appearance of the solution after mixing: clear and colourless or slightly yellow solution.

c. Addition to CLINIMIX (see section 6.2 also)
To perform an addition:
• Aseptic conditions must be observed.
• Ensure stability and compatibility of additives.
• Activate the chambers of bag prior to introduction of additives.
• Prepare the injection port site of the bag.
• Puncture the injection port site and inject the additives using an injection needle or a reconstitution device.
• Mix the content of the bag and the additives thoroughly.
• Inspect final solution for discoloration and particulate matter.
• Check bag for leaks.
• Ensure proper storage requirements of additives are followed.

d. Addition of lipid emulsion
For the addition of lipids with a syringe or a transfer set fitted with a needle:
- Prepare the injection port site (see Figure 1).
- Puncture the port site and inject.
- Mix the solutions and the additives.

As with all parenteral solutions, compatibility should be checked when additives are used. Thorough and careful aseptic mixing of any additives is mandatory.

Warning***:*** The supplementation can be made, after opening the peel seals (once the two solutions have been mixed) for all additives. CLINIMIX may be supplemented with:

- Lipid emulsions (for example CLINOLEIC®) at a rate of 50 to 250 ml per litre of CLINIMIX

	CLINIMIX N12G20 - 1 l + 100 ml lipids 20%	CLINIMIX N12G20 - 1.5 l + 250 ml lipids 20%	CLINIMIX N12G20 - 2 l + 250 ml lipids 20%

Nitrogen (g) Amino acids (g) Glucose (g) Lipids (g)	5.8 35 100 20	8.7 53 150 50	11.6 70 200 50
Total calories (kcal) Glucose calories (kcal) Lipid calories (kcal) Glucose/lipids Ratio	740 400 200 67/33	1310 600 500 55/45	1580 800 500 62/38
Acetate (mmol) Chloride (mmol)	27 15	41 22	54 29
pH Osmolarity (mOsm/l)	6 860	6 830	6 850

- Electrolytes: per litre of CLINIMIX

	Sodium	Potassium	Magnesium	Calcium
Up to a final concentration of	80 mmol	60 mmol	5.6 mmol	3.0 mmol

- Trace elements: per litre of CLINIMIX

Up to a final concentration of	Copper	10 µmol	Zinc	77 µmol
	Chromium	0.14 µmol	Manganese	2.5 µmol
	Fluorine	38 µmol	Cobalt	0.0125 µmol
	Selenium	0.44 µmol	Molybdenum	0.13 µmol
	Iodine	0.5 µmol	Iron	10 µmol

- Vitamins: per litre of CLINIMIX

Up to a final concentration of	vitamin A	1750 IU	Biotin	35 µg
	vitamin B6	2.27 mg	vitamin B1	1.76 mg
	vitamin D	110 IU	Folic acid	207 µg
	vitamin B12	3.0 µg	vitamin B2	2.07 mg
	vitamin E	5.1 mg	vitamin C	63 mg
	vitamin PP	23 mg	vitamin B5	8.63 mg
	vitamin K	75 µg		

Stability data for supplementation of CLINIMIX with other marketed lipid emulsions and other additives or nutrients are available upon request.

If some light creaming is observed, mix thoroughly the admixture by gentle agitation to get a uniform emulsion before the infusion.

e. <u>Preparation for administration</u>

- Suspend the container.
- Remove the protective cover from the administration port site (see Figure 1).

- Firmly insert the administration set spike into the administration port site.
- For single use only. Do not store partly used containers and discard all equipment after use. Do not reconnect partially used bag. Do not connect in series in order to avoid air embolism due to possible residual air contained in the primary bag.

f. Administration

For single use only.
Only administer the product after the non-permanent seal between the two compartments have been broken and the contents of the two compartments have been mixed.
Do not reconnect any partially used bag.
Do not connect bags in series in order to avoid air embolism due to possible residual air contained in the primary bag.
Use of a final filter is recommended during administration of all parenteral nutrition solutions, where possible.

Any unused product or waste material should be disposed of in accordance with local requirements.

When used in neonates and children below 2 years, protect from light exposure, until administration is completed. Exposure of CLINIMIX to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see sections 4.2, 4.4 and 6.3).

Figure 1 Bag Design

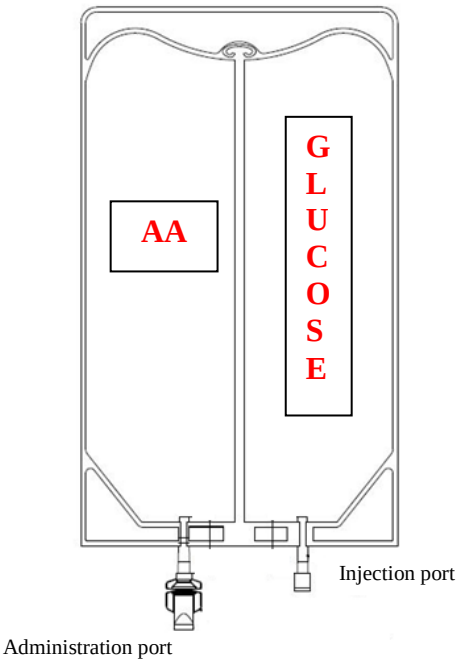

Figure 2 Squeezing or Rolling of CLINIMIX bag

1. 	2. 	3. 
Tear from the top to open the overpouch.	Peel the front of the overpouch to reveal the CLINIMIX bag. Discard the overpouch and oxygen absorber sachet.	Place the bag flat on a horizontal and clean surface with the handle in front of you.
4. 	5. 	6. 
Lift the hanger area to remove the solution from the top of the bag. Firmly roll the bag until the peal seal is fully open (approximately half way).	Mix by turning the bag upside-down at least 3 times.	Hang the bag. Twist off the protector from the administration outlet. Firmly plug the spike connector.

7 MARKETING AUTHORISATION HOLDER

Baxter Healthcare Ltd.,

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Thetford,

Norfolk

1P24 3SE

U.K.

8. MARKETING AUTHORISATION NUMBER

PL 00116/0302

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/12/2009

10 DATE OF REVISION OF THE TEXT

08/09/2021