CLINIMIX® N9G15E 1000 mL
Amino acids solution with electrolytes, Glucose solution with calcium

Infus

PROPERTIES

CLINIMIX® solutions are sterile, aqueous, non pyrogenic solutions for intravenous infusion. The solutions are packaged in a dual compartment bag; one compartment contains 500 mL of amino acids solution with electrolytes; the other compartment contains 500 mL of glucose solution with calcium. Both compartments are separated by a peal seal. Just before administration, the contents of both chambers are mixed by squeezing the top compartment to break the seal.

CLINIMIX® N9G15E contains :

- Nitrogen 9 g (5.5% amino acids with electrolytes)
- Glucose 15% with calcium

Sterile aqueous solution for intravenous infusion

INDICATIONS

CLINIMIX® solutions provide a biologically available source of nitrogen (L-amino acids), energy (as glucose) and electrolytes.

The therapeutic indications are parenteral nutrition when oral or enteral alimentation is impossible, insufficient or contra-indicated.

COMPOSITION

Characteristics of the mixture (1 Litre) : hypertonic 845 mOsm/L, pH 6.0

Nitrogen : 4.55 g Total calories : 410 Kcal Glucose calories : 300 Kcal

	Compartment of amino acids 5.5%+ electrolytes (500ml)	Compartment of Glucose 15% + calcium chloride (500 ml)	Mixtured amino acids 5.5% (500 ml)+ glucose 15% (500 ml)+ electrolytes
Active ingredients			
L-alanine	5.690 g		5.690 g
L-arginine	3.165g		3.165 g
Glycine	2.835 g		2.835 g
L-histidine	1.320g		1.320 g
L-isoleucine	1.650g		1.650 g
L-leucine	2.010g		2.010 g
L-lysine as hydrochloride	1.995g		1.995 g
L-methionine	1.100g		1.100 g
L-phenylalanine	1.540g		1.540 g
L-proline	1.870g		1.870 g
L-serine	1.375g		1.375 g
L-threonine	1.155g		1.155 g
L-tryptophan	0.495 g		0.495 g
L-tyrosine	0.110 g		0.110 g
L-valine	1.595g		1.595 g
Sodium acetate $3H_20$	2.155g		2.155 g
Dibasic potassium phosphate	2.610g		2.610 g

Sodium chloride	1.120g		1.120 g
Magnesium chloride $6H_20$	0.510 g		0.510 g
Glucose anhydrous as monohydrate		75 g	75g
Calcium chloride $2H_20$		0.331 g	0.331 g
Other ingredients			
Acetic acid, qs	pH		pH
Hydrochloric acid, qs		pH	pH
Water for injections, qs	500 ml	500 ml	1 L

DOSAGE AND ADMINISTRATION

1. Dosage and rate infusion :
   The dosage is chosen according to the metabolic needs, the energy expenditure and the clinical status of the patient.
   In adults, the requirements range from 0.16 g of nitrogen/kg/d (1 g of amino acid/kg/d) to 0.35 of nitrogen/kg/d (2 g of amino acid/kg/d).
   The calorie requirements range from 30 to 40 Kcal/kg/d, depending on the nutritional status of the patient and the degree of catabolism.
   To fully metabolize the amino acids it is recommended that these solutions are administered in conjuction with 500 mL of 20% lipid emulsion.
   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.
2. Route of administration :
   The amino acid and glucose solutions should be infused via a central vein.
   The amino acid and glucose solutions are usually administered together with a lipid emulsion; the tertiary mixtures may be infused via a peripheral or central vein depending on their final osmolarity, see table enclosed.

OVERDOSAGES

In cases of incorrect administration (dosage and rate), signs of hypervolemia and acidosis may be observed; discontinue the infusion immediately.
In some serious cases haemodialysis, haemodiafiltration may be necessary.

WARNINGS AND PRECAUTIONS

Special clinical monitoring is required at the beginning of any intravenous infusion.
Should any abnormal signs occur, the infusion must be stopped.
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.
Frequent clinical evaluation and laboratory determinations are necessary for correct monitoring during administration. These should include blood sugar, ionogram and kidney and liver function tests.
The electrolyte requirements of patients receiving the solutions should be carefully determined and monitored especially for the solutions with electrolyte.
Administration to diabetics should be monitored closely. With the infusion of the products, hyperglycaemia, glycosuria, and hyperosmolar syndrome may be occur. Blood and urine glucose should be monitored on a routine basis and insulin dosage should be adapted, if necessary.
Care should be taken to avoid circulatory overload particularly in patients with cardiac insufficiency and/or failure.
In patients with hepatic insufficiency, apart from routine liver function tests, possible symtomps of hyperammonaemia should be controlled.

Solutions containing electrolytes must be infused with caution in patients with abnormally high serum levels of these elements, especially in patients with impaired renal function.

If the infusion is not continuous over 24 hours, keep to an appropriate infusion rate; possibly with a gradual increase in the first hour and a gradual decrease in the last hour to avoid abnormal glycaemic peaks.
Administration of amino acid solutions may cause acute folate deficiency and supplementary folic acid should be administered.
Vitamin B12 status should be monitored and supplementation given if necessary.

USES IN PREGNANCY AND LACTATION

The safety of **CLINIMIX®** in pregnancy and lactation has not been proven due to the lack of clinical studies. The decision to administer **CLINIMIX®** to pregnant or breast feeding women therefore remains the responsibility of the prescriber.

PHARMACEUTICAL PRECAUTIONS

1. Store below 25°C. Do not freeze.
2. Do not remove from overpouch until ready to use.
3. Administer the product only after breaking the seal and mixing the contents of both compartments.
4. For single use only. Do not store partly used containers and discard all equipment after use. Do not use unless solution clear and container undamaged.
5. As with all parenteral solutions, compatibility should be checked when additives are used.
6. Additives may be incompatible; refer to PT KALBE FARMA Tbk. for further details.
7. Thorough and careful aseptic mixing of any additives is mandatory.
8. The solution should not be administered simultaneously with, before or after and administration of blood, through the same infusion equipment because of the possibility of pseudo-agglutination.
9. Do not connect in series in order to avoid air embolism due to possible residual air contained in the primary bag.

SIDE EFFECTS

- The potential undesirable effects arise from inadequate conditions of use for example too high dosage, too rapid infusion (see Warnings and Precautions).
- Nausea may occasionally occur.
- If the recommended infusion rate is exceeded, vomiting, sweating and flushing may occur.
- Abnormal results on liver function test and cholestasis have been reported in some patients receiving parenteral nutrition.

CONTRAINDICATIONS

- Known hypersensitivity to any of the ingredients.
- Renal failure in the absence of haemodialysis.
- Haemofiltration or haemo-dia-filtration.
- Severe liver disease.
- Patients with abnormally high serum electrolyte levels.

DIRECTIONS FOR USE

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.

1. 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.

2. 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 1).
- Mix by inverting the bag 2 or 3 times.
- Appearance of the solution after mixing: clear and colourless or slightly yellow solution.

Storage : The binary admixture is stable for 7 days at 2 - 8°C, followed by 48 hours below 25°C. Do not freeze. Following additions, the admixture should not be kept for more than 24 hours at 2 - 8°C.

3. Addition to **CLINIMIX®**

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 site of the bag.
- Puncture the injection 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.

Warning: As with all parenterals, compatibilities should be checked when additions are to be made. Additives may be incompatible, refer to PT KALBE FARMA Tbk. for further details.
Additions should be performed under aseptic conditions. Additions can be made through the medication injection site with a needle or a transfer set.

1

Tear from the top to open the overpouch.

2.

Peel the front of the overpouch to reveal the **CLINIMIX®** bag. Discard the overpouch and oxygen absorber sachet.

3.

Place the bag flat on a horizontal and clean surface with the handle in front of you.

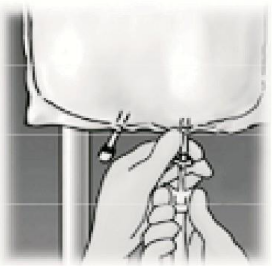
4.

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).

5.

Mix by turning the bag upside down at least 3 times.

6



Hang the bag. Twist off the protector from the administration outlet. Firmly plug the spike connector.

Figure 1. Grasp the container firmly on each side of the top of the bag. Squeeze or roll to break seal.

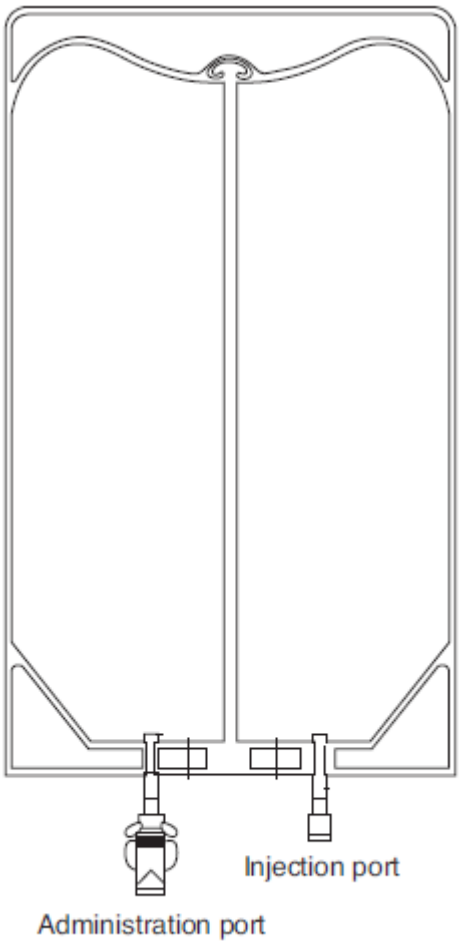


Figure 2

Manufactured by:
BAXTER S.A.
Boulevard René Branquart, 80
7860 Lessines Belgium

Imported & marketed by:
PT KALBE FARMA Tbk.
Bekasi - Indonesia
Reg. No. DKI9852300749A1

ON MEDICAL PRESCRIPTION ONLY.

KALBE