Important Prescribing Information

November 8, 2017

Subject: Temporary importation of intravenous drug products to address drug shortages

Dear Healthcare Professional,

Due to the critical shortage of drug products resulting from Hurricane Maria, Baxter Healthcare Corporation (Baxter) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of products from Baxter's manufacturing facility in the United Kingdom (UK).

Baxter has initiated temporary importation of the products tabulated below. These products are manufactured by Baxter's manufacturing facility in the UK and marketed in the UK. At this time, no other entity except Baxter is authorized by the FDA to import or distribute these products in the United States. FDA has not approved the listed products manufactured by Baxter's manufacturing facility in the UK.

Effective immediately, and during this temporary period, Baxter will offer the following:

Product name and description	Size	Product code	Pack Factor	NDC
CLINIMIX N9G15E-Solution for Infusion **5.5% Amino Acids with Electrolytes (500 mL) and Glucose 15% with Calcium (500 mL)** for a final mixture 2.75% Amino Acid in 7.5% Glucose with Electrolytes	1,000 mL	FKB6669C	8	0338-9570-08
CLINIMIX N9G20E-Solution for Infusion **5.5% Amino Acids with Electrolytes (500 mL) and Glucose 20% with Calcium (500 mL)** for a final mixture of 2.75% Amino Acid in 10% Glucose with Electrolytes	1,000 mL	FKB6670C	8	0338-9566-08
CLINIMIX N14G30E-Solution for Infusion **8.5% Amino Acids with Electrolytes (1000 mL) and Glucose 30% with Calcium (1000 mL)** for a final mixture of 4.25% Amino Acid in 15% Glucose with Electrolytes	2,000 mL	FKB6654V	4	0338-9587-04

It is important to note the following:

- Consider the nutritional needs and clinical status of the patient, and the differences in formulation between the U.S. marketed products and the imported products, when selecting the appropriate dosage.
  - The three imported CLINIMIX-Solution for Infusion products may not be appropriate alternatives for all of the US-approved CLINIMIX products. Each formulation contains a different mixture of amino acids and glucose.
  - The amounts of individual ingredients may differ between the imported CLINIMIX-Solution for Infusion products and the U.S. marketed products. Please refer to the imported CLINIMIX-Solution for Infusion product composition in the product information tables at the end of this letter. Please also refer to the FDA-approved package insert for the composition of CLINIMIX E sulfite-free Injections marketed in the U.S.

- **The expression of the concentrations is different for individual ingredients on the imported CLINIMIX-Solution for Infusion products.** The imported products state the ingredient concentrations contained within each chamber of the CLINIMIX-Solution for Infusion dual-chamber bags **before** mixing. In comparison, the product names for the U.S. marketed CLINIMIX E sulfite-free Injections indicate the amino acid and dextrose concentrations **after** mixing the two chambers.

- The imported CLINIMIX-Solution for Infusion product name is based on the initial concentration of the base solutions before mixing. The amino acid chamber is represented by the nitrogen (N) content in grams per liter (g/L), the glucose (G) chamber is represented as the initial concentration of the glucose solution before mixing, and electrolytes (E) are included in the formulation.

  As an example with CLINIMIX N9G15E-Solution for Infusion:

  - N9 represents 9 g/L of Nitrogen within the amino acids chamber, which is approximately 4.5 g of nitrogen in 500 mL.
  - G15 indicates that there is a 15% glucose solution in the glucose chamber
  - E indicates that a standard electrolyte profile has been added

- **This product has not been tested for aluminum content and this should be taken into consideration when administering to preterm and term infants less than 1 month of age and patients with renal impairment.**

- The imported CLINIMIX-Solution for Infusion product does not contain added sulfites and is considered sulfite-free.

- **The osmolarity of a specific infusion solution** must be taken into account when peripheral administration is considered. The label of the imported CLINIMIX-Solution for Infusion product from the UK states that a solution with an osmolarity above 800 mOsm/L should be infused via a central vein.

- For CLINIMIX-Solution for Infusions supplied in a clear overpouch, **keep container in the outer carton in order to protect from light**.

- **The storage instructions differ** between the imported CLINIMIX-Solution for Infusion from the UK and the U.S. marketed CLINIMIX E sulfite-free Injections. Please refer to the product label for appropriate storage.

- **Prior to use, it is important to check for leaks** by squeezing the inner bag firmly. If leaks are found, discard solution as sterility may be impaired. Additionally, check to see that solution is clear and free of foreign matter. Discard the solution if solution is not clear.

- **The barcode may not register accurately on the U.S. scanning systems.** Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

- **The injection/medication ports and port protectors are similar** between the CLINIMIX products marketed in the US and the imported CLINIMIX products and are compatible with Baxter IV and transfer sets marketed in the United States. The imported product has a white twist-off port protector, whereas the US-approved product has a blue twist-off port protector.

Please see the product comparison table at the end of this letter for the key differences between the imported CLINIMIX- Solution for Infusion products.

Please refer to the FDA-approved package insert for the full prescribing information of CLINIMIX E sulfite-free (Amino Acids with Electrolytes in Dextrose with Calcium) Injections at: https://www.dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=8469d6fb-d6ef-476f-8cc3-0905192de0a8&type=pdf&name=8469d6fb-d6ef-476f-8cc3-0905192de0a8

If you have any questions about the information contained in this letter or the use of the imported products, please contact Baxter's Medical Information Service at 1-800-933-0303.

To place an order, please contact Baxter's Center for Service by calling 1-888-229-0001.

To report product quality issues please contact Baxter Product Surveillance at 1-800-437-5176.

To report adverse events associated with these imported products, please call Baxter at 1-866-888-2472, or fax: 1-800-759-1801. Adverse events or quality problems experienced with the use

of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Sincerely,

Dennis Vaughn

Vice President, Marketing Operations

Baxter Healthcare Corporation

USMP/78/17-0020 11/17

Product Information Tables

Table 1. Imported Clinimix-Solution for Infusion

<table>
<tr><th></th><th>Import Product</th></tr>
<tr><th></th><th>CLINIMIX-N9G15E-Solution for Infusion / CLINIMIX-N9G20E-Solution for Infusion / CLINIMIX-N14G30E-Solution for Infusion</th></tr>
<tr><td>Description</td><td>CLINIMIX N9G15E, N9G20E and N14G30E solution is a sterile, aqueous, non-pyrogenic solution for intravenous infusion. The solution is packaged in a dual compartment plastic bag containing respectively an amino acid solution with electrolytes and a glucose solution with calcium.</td></tr>
<tr><td>Indication for Use</td><td>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.</td></tr>
<tr><td>Dosage and Administration</td><td>Dosage and rate of 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 (approximately 1 g of amino acid/kg/d) to 0.35 g of nitrogen/kg/d (approximately 2 g of amino acid/kg/d).
In infants, the requirements range from 0.35 g of nitrogen/kg/d (approximately 2 g of amino acid/kg/d) to 0.45 g of nitrogen/kg/d (approximately 3 g of amino acid/kg/d).
The 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.
The maximum daily doses of each constituent of CLINIMIX N9G15E, N9G20E and N14G30E (i.e., amino acids and glucose) should be based on individual total nutritional requirements and patient tolerance.
The maximum infusion rate and the maximum daily dose vary according to the different combinations and are provided in the following table:
<table>
<tr><th></th><th>Maximum infusion rate*</th><th>Maximum daily dose*</th></tr>
<tr><td>CLINIMIX N9G15E solution for infusion</td><td>3 mL/kg/hour or
180 mL/hour to 210 mL/hour</td><td>40 mL/kg/day or
2400 mL/day to 2800 mL/day</td></tr>
<tr><td>CLINIMIX N9G20E--solution for infusion</td><td>2.5 mL/kg/hour or
150 mL/hour to 175 mL/hour</td><td>40 mL/kg/day or
2400 mL/day to 2800 mL/day</td></tr>
<tr><td>CLINIMIX N14G30E--solution for infusion</td><td>1.7 mL/kg/hour or
100 mL/hour to 120 mL/hour</td><td>40 mL/kg/day or
2400 mL/day to 2800 mL/day</td></tr>
</table>
* For a patient weighing 60 kg to 70 kg

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.
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
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.
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 hypoglycemia after discontinuation, a gradual decrease in flow rate in the last hour of administration should be considered.</td></tr>
<tr><td>Contraindications and Drug Interactions</td><td>Contraindications:
• Known hypersensitivity to any of the active substances or excipients or to components of the container.
• Amino acid metabolism disorders
• Severe hyperglycemia
• Metabolic acidosis, hyperlactataemia CLINIMIX containing electrolytes) should not be used in patients with hyperkalaemia, hyponatraemia and in patients with pathologically elevated plasma concentrations of magnesium, calcium and/or phosphorus.
• As for other calcium-containing infusion solutions, concomitant treatment with ceftriaxone and CLINIMIX is contraindicated in newborns (≤28 days of age), even if separate infusion lines are used (risk of fatal ceftriaxone calcium salt precipitation in the neonate's bloodstream).
• Because of its potassium content, CLINIMIX should be administered with caution in patients treated with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium-sparing diuretics (amiloride, spironolactone, triamterene), with ACE inhibitors, angiotensin II receptor antagonists, or the immunosuppressants tacrolimus and cyclosporine.</td></tr>
<tr><td>Warnings and Precautions</td><td>Warnings:
Hypersensitivity/infusion reactions including hypotension, hypertension, peripheral cyanosis, tachycardia, dyspnea, 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
In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including CLINIMIX [N9G15E] [N9G20E] [N14G30E] through the same infusion line (e.g., via a Y – connector).
If the same infusion line is used for sequential administration, the line must be thoroughly flushed with a compatible fluid between infusions.
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 hyperglycemia, malnutrition and/or their underlying disease state may predispose patients to infectious complications.</td></tr>
</table>

Import Product

CLINIMIX-N9G15E-Solution for Infusion / CLINIMIX-N9G20E-Solution for Infusion / CLINIMIX-N14G30E-Solution for Infusion

Careful symptomatic and laboratory monitoring for fever/chills, leukocytosis, technical complications with the access device, and hyperglycemia 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 hyponatraemia.

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 edema, cardiac insufficiency and/or failure. Fluid status should be closely monitored.

In patients with preexisting 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 etiology 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 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 etiology, hyperammonemia may require immediate intervention.

A too rapid infusion of amino acid 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

- There have been no studies performed in the pediatric population.

See above regarding monitoring for hyperammonemia in pediatric patients.

Usage in Specific Population

Use in pregnancy and lactation

The safety of CLINIMIX in 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.

Effects on ability to drive and use machines

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

Adverse Events

Potential undesirable effects may occur as a result of inappropriate use: for example, overdose or excessively fast infusion rate.

Post-marketing Adverse Reactions

The following adverse reactions have been reported with CLINIMIX formulations in the postmarketing 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, Dyspnea, 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.

Overdosage

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.

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.

Import Product

CLINIMIX-N9G15E-Solution for Infusion / CLINIMIX-N9G20E-Solution for Infusion / CLINIMIX-N14G30E-Solution for Infusion

Storage Conditions

- 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. Do not freeze.
- For the product supplied in the clear overpouch, keep container in the outer carton in order to protect from light. Do not freeze.
- Store CLINIMIX-Solution for Infusion from the UK at room temperature (25°C/77°F) (may briefly store at up to 40°C/104°F).

Directions for use

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

CLINIMIX solutions are presented in two different bags designs. The direction for use hereafter applies for both designs.

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

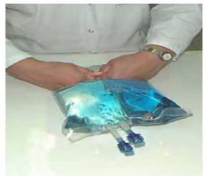
a. To open the overpouch

- 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 to activate (see photo). Product supplied with the vertical peel-seal design may also be activated by rolling (see photos).
- Mix by inverting the bag 2 or 3 times.
- Appearance of the solution after mixing: clear and colourless or slightly yellow solution.

Squeezing or rolling of the vertical CLINIMIX®

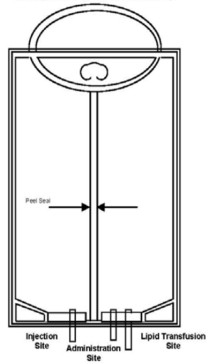


c. Addition to CLINIMIX - To perform an addition:

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

Drawing Of The Vertical Peel Seal Dual Bag



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

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

Additions should be performed under aseptic conditions.

Additions can be made with a syringe or a transfer set.

Addition with a syringe or a transfer set fitted with a needle

. Prepare the injection site (the single port, see drawing).

. Puncture the port and inject.

. Mix the solutions and the additives.

Addition with a transfer set fitted with a spike

. Please refer to the “Directions for use” of the lipid transfer set used.

. Connect the spike to the transfusion site (the longest port)

d. Preparation for administration

Suspend the container.

Remove the protective cover from the administration port site (the smaller port of the pair of the ports of the container, see photos).

Firmly insert the administration set spike into the administration port.

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.

e. 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.

How Supplied

CLINIMIX N9G15E and CLINIMIX N9G20E are available in 1000 mL dual compartment bag. Both bags are separated by a peel seal. CLINIMIX N14G30E is available in 2000 mL dual compartment bag.
CLINIMIX N9G15E-Product Code: FKB6669C NDC: 0338-9570-08

CLINIMIX N9G20E-Product Code: FKB6670C NDC: 0338-9566-08

CLINIMIX N14G30E-Product Code: FKB6670C NDC: 0338-9587-04

Table 2. Imported CLINIMIX-Solution for Infusion product composition

		CLINIMIX-N9G15E-solution for Infusion (final mixture: 2.75% Amino Acid with Electrolytes in 7.5% Glucose with Calcium Injection)	CLINIMIX-N9G20E-Solution for Infusion (final mixture: 2.75% Amino Acid with Electrolytes in 10% Glucose with Calcium Injection)	CLINIMIX N14G30E-Solution for Infusion (final mixture: 4.25% Amino Acid with Electrolytes in 15% Glucose with Calcium Injection)
Active Ingredients (g/L) - for each individual chamber prior to mixing	L- Leucine	4.02	4.02	6.20
	L-Phenylalanine	3.08	3.08	4.76
	L-Methionine	2.20	2.20	3.40
	L-Lysine (as hydrochloride)	3.19 (4.00 as hydrochloride)	3.19 (4.00 as hydrochloride)	4.93 (6.16 as hydrochloride)
	L-Isoleucine	3.30	3.30	5.10
	L-Valine	3.19	3.19	4.93
	L-Histidine	2.64	2.64	4.08
	L-Threonine	2.31	2.31	3.57
	L-Tryptophan	0.99	0.99	1.53
	L-Alanine	11.38	11.38	17.6
	L-Arginine	6.32	6.32	9.78
	Glycine	5.66	5.66	8.76
	L-Proline	3.74	3.74	5.78
	L-Serine	2.75	2.75	4.25
	L-Tyrosine	0.22	0.22	0.34
	Sodium acetate, $3H_2O$	4.31	4.31	5.94
	Dibasic potassium phosphate	5.22	5.22	5.22
	Sodium Chloride	2.24	2.24	1.54
	Magnesium Chloride.$6H_2O$	1.02	1.02	1.02
	Glucose (as monohydrate)	150 (165 as monohydrate)	200 (220 as monohydrate)	300 (330 as monohydrate)
	Calcium Chloride $2H_2O$	0.66	0.66	0.66
After mixing of the contents of both compartments, the composition of the binary mixture, for all the available bag sizes, is the following:		1000 mL	1000 mL	2000 mL
	Nitrogen(g)	4.6	4.6	14.0
	Amino Acids(g)	28	28	85
	Glucose(g)	75	100	300
	Total Calorie(kcal)s	410	510	1540
	Glucose Calories(kcal)	300	400	1200
	Sodium (mmol)	35	35	70
	Potassium (mmol)	30	30	60
	Magnesium (mmol)	2.5	2.5	5.0
	Calcium (mmol)	2.3	2.3	4.5
	Acetate (mmol)	50	50	140
	Chloride (mmol)	40	40	80
	Phosphate as HPO_4^{--}(mmol)	15	15	30
	pH	6	6	6
	Osmolarity (mOsm/l)	845	980	1415

Table 3. Imported CLINIMIX-Solution for Infusion product labels

CLINIMIX-N9G15E-solution for Infusion (final mixture: 2.75% Amino Acid with Electrolytes in 7.5% Glucose with Calcium Injection)	CLINIMIX-N9G20E-Solution for Infusion (final mixture: 2.75% Amino Acid with Electrolytes in 10% Glucose with Calcium Injection)	CLINIMIX N14G30E-Solution for Infusion (final mixture: 4.25% Amino Acid with Electrolytes in 15% Glucose with Calcium Injection)