PACKAGE LEAFLET

Package leaflet: Information for the patient

Pedismof Neonate and Infant emulsion for infusion

Read all of this leaflet carefully before your child is given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your childs' doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pedismof Neonate and Infant is and what it is used for

Pedismof Neonate and Infant is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (preterm and term) and children up to two years of age. It is given into your child's blood by a drip (intravenous infusion) when your child is not able to eat all his or her food by mouth.

Pedismof Neonate and Infant contains amino acids (components used to build proteins), electrolytes (salts), glucose (carbohydrates) and lipids (fat).

Pedismof Neonate and Infant is presented in the form of a three chamber plastic bag. The respective chambers contain:
- a 6.5% amino acid solution with electrolytes
- a 19.6% glucose solution
- a 20% lipid emulsion

The doctor may choose not to give lipids to your child. If this is the case, only two of the three chambers (the glucose and amino acid chamber, two chamber bag) will be mixed in the bag before it is given to your child.

Pedismof Neonate and Infant must only be used under medical supervision.

2. What you need to know before your child is given Pedismof Neonate and Infant

Your child should not be given Pedismof Neonate and Infant, in the following cases:
With the glucose and amino acid solutions mixed in the bag (two chamber bag activation):
- if your child is allergic to egg, fish, soya, peanuts or any of the active substances or other ingredients of this medicine (listed in section 6)
- if your child has congenital problems with using and metabolising amino acids
- if your child has too much sugar in the blood (hyperglycaemia)
- if your child has too much salts in the blood
- if your child is newborn (28 days of age or less) Pedismof Neonate and Infant (or other calcium-containing solutions) must not be given at the same time as ceftriaxone (an antibiotic), even if separate infusion lines are used. There is a risk of particle formation in your child's bloodstream which may be fatal.

With the glucose, amino acid solutions and lipid emulsions mixed in the bag (three chamber bag activation).
All the above situations mentioned for the two chamber bag activation plus the following:
- if your child has too much lipids (hyperlipidemia) or triglycerides (hypertriglyceridemia) in the blood

Warnings and precautions
Talk to the doctor before your child is given Pedismof Neonate and Infant if your child has:
- kidney problems
- diabetes mellitus
- liver problems
- serious infection (sepsis)
- fluid in the lungs (pulmonary oedema) or heart failure

If your child during the infusion gets fever, rash, swelling, difficulty in breathing, chills, sweating, nausea or vomiting, tell the healthcare professional immediately because these symptoms might be caused by an allergic reaction or that your child have been given too much of the medicine.

Your child's doctor will regularly check your child's blood for liver function tests and other values.

Other medicines and Pedismof Neonate and Infant
Tell your child's doctor if your child is taking, has recently taken or might take any other medicines.

The doctor will closely monitor your child if he or she is taking anticoagulants, such as coumarin or warfarin, which prevent blood clotting. Olive and soybean oils naturally contain a small amount of vitamin K1, which can interfere with these medicines.

If your child is newborn (28 days of age or less), your doctor will make sure that Pedismof Neonate and Infant (or other calcium containing solutions) is not given together with ceftriaxone (an antibiotic), even if separate infusion lines are used. There is a risk of particle formation in your child's bloodstream which may be fatal.

3. How Pedismof Neonate and Infant is given

Your child's doctor will decide on the dose depending on the body weight and function of your child. Pedismof Neonate and Infant will be given to your child by a healthcare professional.

This medicine is an emulsion for infusion. It is given through a plastic tube in a large vein in your child's chest.

The doctor may choose not to give lipids to your child. The design of the Pedismof Neonate and Infant bag allows only the peel seal between the amino acid and glucose chambers to be broken if necessary. The peel seal between the amino acids and lipid chambers remains intact in this case. The content of the bag can then be infused without lipids. The glucose chamber should never be administered alone.

Age group
Pedismof Neonate and Infant is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (preterm and term) and children up to two years of age. It is given into your child's blood by a drip (intravenous infusion) when your child is not able to eat all his or her food by mouth.

Pedismof Neonate and Infant may not be appropriate for some preterm new-born babies, as their condition may require individualized formulations to meet their specific nutritional needs. The doctor

will decide if this medicine is suitable for your child.

If your child is given too much Pedismof Neonate and Infant
It is unlikely that your child will receive too much medicine as Pedismof Neonate and Infant is given to your child by a healthcare professional. Nevertheless, please see section 4 for possible signs and symptoms of too much fat, amino acids and/or glucose.

If you have any further questions on the use of this medicine, ask your child's doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not every child gets them.

If you notice any changes in the way your child feels during or after the treatment, tell the doctor or nurse immediately.

If the side effects occur, the infusion of Pedismof Neonate and Infant may need to be stopped or continued at a reduced rate/dosage by the health care professional.

The tests the doctor will perform while your child is taking the medicine should minimize the risk of side effects.

Common: may affect up to 1 in 10 people
- High levels of fat (called triglycerides) in the blood, leading to a condition known as hypertriglyceridemia.
- High blood sugar levels (hyperglycemia), which may require monitoring or treatment.

Uncommon: may affect up to 1 in 100 people
- High levels of fat (called lipids) in the blood, leading to a condition known as hyperlipidaemia.
- A condition where bile (a fluid made by the liver) cannot flow properly to the intestine (cholestasis).
- Fever (pyrexia).

Not known: frequency cannot be estimated from the available data
- High levels of bilirubin in the blood (hyperbilirubinemia), which may lead to yellowing of the skin or eyes (a condition called jaundice).

The following side effects have been reported with other parenteral nutrition admixtures.

Fat overload syndrome
Fat overload syndrome is a rare condition which is caused by a reduced or limited ability to remove the lipids contained in Pedismof Neonate and Infant. The following signs and symptoms of this syndrome are usually reversible when the infusion of the lipid emulsion is stopped:
- Sudden and abrupt worsening of the patient's medical condition
- High levels of fats in the blood (hyperlipidemia)
- Fever
- Liver fatty infiltration (hepatomegaly)
- Worsening liver function
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anemia)
- Low white blood cell count, which can increase the risk of infection (leukopenia)
- Low platelet count which can increase the risk of bruising and/or bleeding (thrombocytopenia)
- Coagulation disorders which effect the ability of the blood to clot
- Coma, requiring hospitalisation

Amino acid related side effects
The amino acids in Pedismof Neonate and Infant may cause side effects when too much of the medicine is given to your child. These effects may be nausea, vomiting, shivering, and sweating. Amino acid infusion may also cause a rise in body temperature.

Glucose related side effects
If too much glucose is given to your child, your child will have too much sugar in the blood (hyperglycaemia) and in the urine (glucosuria). This can lead to a condition called hyperosmolar syndrome.

Reporting of side effects
If your child gets any side effects, talk to the doctor or the nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Pedismof Neonate and Infant

Keep this medicine out of the sight and reach of children..

Do not store above 25°C. Do not freeze. Store in overpouch.

Do not use this medicine after the expiry date which is stated on the carton or bag label after EXP . The expiry date refers to the last day of that month.

When used in new-born babies and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed.

6. Contents of the pack and other information

What Pedismof Neonate and Infant contains
See information intended for health care professional at the end of the package leaflet.

What Pedismof Neonate and Infant looks like and contents of the pack
Pedismof Neonate and Infant, emulsion for infusion consists of a three chamber bag system where one chamber contains an amino acid solution, one contains a glucose solution and one contains lipid emulsion.

Container size	Amino acid solution, 6.5% with electrolytes	Glucose 19.6%	Lipid emulsion 20 % (SMOFlipid)
500 ml	191 ml	255 ml	54 ml

Depending on your child's needs, the solutions from two or three chambers are mixed in the bag before it is given to your child.

Appearance before mixing:
Glucose- and amino acid solutions are clear, colourless or slightly yellow and free from particles. The lipid emulsion is white and homogenous.

Appearance after mixing:
The activated two chamber bag solution for infusion is clear, colorless or slightly yellow and free from particles.

The activated three chamber bag emulsion for infusion is uniform and milky-white.

An oxygen absorber and an integrity indicator are placed between the primary bag and the overpouch.

Pack sizes:
6 x 500 ml

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer:
Fresenius Kabi AB, SE-751 74 Uppsala, Sweden

This leaflet was last revised in August 2025.

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The following information is intended for healthcare professionals only:

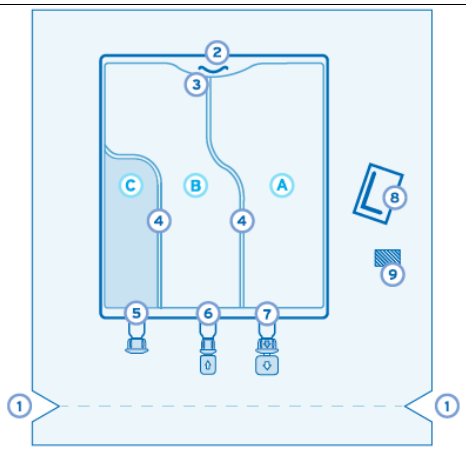
Special precautions for disposal and other handling
No additions to the bag should be made without first checking the compatibility (see table 3 and 4 below).

For single use only.

Any unused medicinal product or waste material should be disposed in accordance with local requirement.

Instructions for use

Schematic overview of the bag

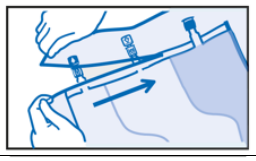
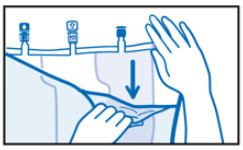
1. Notches in the overpouch 2. Handle 3. Hole for hanging the bag 4. Peelable seals 5. Blind port (do not use this port) 6. Additive port (white) 7. Infusion port (blue) 8. Oxygen absorber* 9. Integrity indicator* *placed between the bag and the overpouch A. Glucose B. Amino acids C. Lipids	

1. Inspection of the bag

- The integrity indicator should be inspected before removing the overpouch. If the indicator is entirely black, the overpouch is damaged and the product should be discarded. If the indicator has any other colour than solid black, the product is safe to use.

- Use only if the amino acid and glucose solutions are clear and colourless or slightly yellow and the lipid emulsion is white and homogenous.

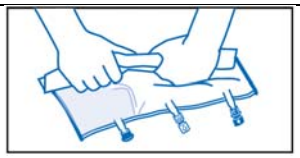
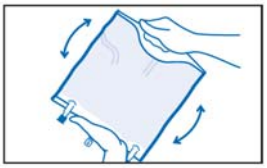
2. Removal of overpouch

• To remove overpouch, hold the bag horizontally and tear from the notch close to the ports along the upper edge.	
• Then simply tear the long side, pull off the overpouch and discard it along with the oxygen absorber and the integrity indicator.	

3. Mixing

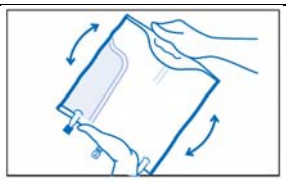
The bag design allows for the activation of 3 chambers (lipids, amino acids, glucose) or 2 chambers (amino acids and glucose only) depending on the patient need.

3.1 Activation of the 3 chambers (mixing of 3 solutions by breaking two peelable seals)

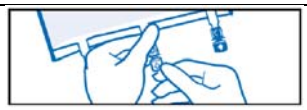
• Place the bag on a clean, flat surface with text side up and ports pointing away from you.	
• Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seals are broken.	
• The amino acids and glucose chambers should be mixed together before the lipid chamber. The vertical peel seals open due to the pressure of the fluid.	
• Mix the contents of the three chambers by inverting the bag three times until the components are thoroughly mixed (entire contents are white). *The liquids mix easily although the verticals seals remain partly closed.*	

3.2 Activation of the 2 chambers (mixing of 2 solutions by breaking the peelable seal between the amino acid and glucose chamber)

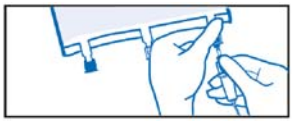
• Place bag on a clean, flat surface with text side up and ports pointing away from you.	

• Roll up the bag tightly from the handle side towards the ports, firstly with the right hand and then applying a constant pressure with the left hand until the vertical seal between the amino acid and glucose chamber is broken. The vertical peel seals open due to the pressure of the fluid. *Do not apply pressure on the peelable seals next to the lipid chamber so that this chamber is not activated.*	
• Mix the contents of the two chambers by inverting the bag three times until the components are thoroughly mixed (a clear solution). *The liquids mix easily although the vertical seal remains partly closed.*	

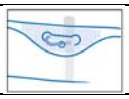
4. Additions (if prescribed)

• Place the bag on a flat surface again. Shortly before injecting additives, break off the white additive port cap with the arrow pointing toward the bag.	
• Hold the base of the additive port. Insert the needle through the centre of the additive port's septum and inject the additives (with known compatibility). • Mix thoroughly between each addition by inverting the bag three times. *The membrane of the additive port is sterile at first use. Use aseptic technique for the additions.*	

5. Finalising the preparation

• Immediately before inserting the infusion set, break off blue infusion port cap with the arrow pointing away from the bag.	
• Hold the base of the infusion port. Push the spike through the infusion port by rotating your wrist slightly until the spike is inserted. The spike should be fully inserted to secure it in place. *The membrane of the infusion port is sterile at first use.* *Use a non-vented infusion set or close the air-inlet on a vented set.*	

6. Hanging up the bag

• Hang the bag by the hole below the handle.	

Warnings and precautions for use

Infusion rates
To avoid risks associated with too rapid infusion rates, it is recommended to use a continuous and well-controlled infusion, if possible, by using a volumetric pump.

Refeeding syndrome
Administering PN to low-birth-weight neonates with very low electrolyte stores may result in refeeding syndrome, which is characterized by low serum potassium, phosphorus, and magnesium levels. Thiamine deficiency and fluid retention may also develop. To prevent these complications, careful and slow initiation of PN with adequate supply of calcium, phosphate, and potassium is recommended with close monitoring of fluids and electrolytes.

Infection
Since an increased risk of infection is associated with the use of intravenous catheters, strict aseptic precautions should be taken to avoid any contamination especially during catheter insertion and manipulations.

Extravasation
Extravasation may occur in all intravenous infusions. The catheter insertion site should be evaluated daily for local signs of extravasation.

Light protection
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 infants below 2 years, Pedismof Infant should be protected from ambient light until administration is completed.

Monitoring/laboratory tests
Throughout treatment, monitor fluid and electrolyte status, acid-base balance, serum osmolarity, serum triglycerides, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets.

Hypersensitivity reactions
Any sign or symptom of anaphylactic reaction (such as fever, shivering, sweating, rash, or dyspnoea) should lead to immediate interruption of the infusion.

Patients with renal impairment
Use with caution in patients with renal insufficiency. Fluid and electrolyte status should be closely monitored in these patients. Severe water and electrolyte disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion of Pedismof Neonate and Infant.

Patients with cardiovascular disorders
Use with caution in patients with pulmonary oedema or heart failure. Fluid status should be closely monitored.

Patients with hepatobiliary disorders
Use with caution in patients with severe liver insufficiency or elevated liver enzymes. Liver function parameters should be closely monitored.

Patients with unstable conditions
In case of unstable conditions (e.g., following severe post-traumatic conditions, decompensated diabetes mellitus, acute phase of circulatory shock, acute myocardial infarction, severe metabolic acidosis, severe sepsis, and hyperosmolar coma), the infusion of Pedismof Neonate and Infant should be monitored and adjusted to meet the clinical needs of the patient.

Specific needs of some preterm neonates
Pedismof Neonate and Infant may not be appropriate for some preterm neonates, as the clinical condition of the patient may require administration of individualized, tailor-made formulations to meet the specific needs of the patient.

Vitamin E / Tocopherol
Soya-bean oil, medium-chain triglycerides, olive oil, and fish oil naturally contain varying amounts of vitamin E (tocopherol). Also added is all-rac-α-tocopherol (another form of vitamin E) to limit lipid peroxidation.
When Pedismof Neonate and Infant is used as a three chamber bag, the content of vitamin E in the activated three chamber bag is 2.9 – 4.1 mg per 250 mL and 11.4 – 16.4 mg per 1000 mL. When Pedismof Neonate and Infant is used as two chamber bag (without activated lipid compartment), no vitamin E (tocopherol) is contained.

Method of administration
Intravenous use, infusion into a central vein.

Electrolytes, vitamins, and trace elements can be added according to the physician's judgment if compatibility is confirmed and according to the clinical needs of the patient, see compatibility below. Upon admixing vitamins, trace elements, or other additives, the final osmolarity of the mixture must be considered before selecting the route of infusion. See detailed instructions on how to calculate osmolarity in the compatibility headline below.

Posology
Recommended dosage and maximum daily dose
The dosage depends on energy expenditure, the patient's body weight, age, clinical status, and on the ability to metabolize the constituents of Pedismof Neonate and Infant, as well as on additional energy or macronutrients given orally/enterally. In paediatric patients requiring parenteral nutrition, lipids are an integral part of parenteral nutrition.

As shown in Table 1, total macronutrient composition depends on the number of activated chambers. The activated three chamber bag contains lipids, amino acids, and glucose. The activated two chamber bag contains amino acids and glucose.

For the activated three chamber bag, the recommended dosage is 60 to 140 mL/kg/d in preterm neonates, 60 to 120 mL/kg/d in term neonates, and 80 to 100 mL/kg/d in infants (Table 1). The dose can be increased gradually over the first days. The maximum recommended daily dosage of 140 mL/kg in preterm neonates, 120 mL/kg in term neonates, and 100 mL/kg/d in infants should not be exceeded.

For the activated two chamber bag, the recommended dosage is 54 to 125 mL/kg/d in preterm neonates, 54 to 107 mL/kg/d in term neonates, and 71 to 89 mL/kg/d in infants (Table 1). The dose can be increased gradually over the first days. The maximum recommended daily dosage of 125 mL/kg in preterm neonates, 107 mL/kg in term neonates, and 89 mL/kg in infants should not be exceeded.

Table 1 Overview of Recommended Dosage for Activated three chamber bag and two chamber bag (units/kg/d) by Component

	Activated three chamber bag			Activated two chamber bag		
	Preterm neonates	**Term neonates**	**Infants**	**Preterm neonates**	**Term neonates**	**Infants**
Fluid (mL)	60-140	60-120	80-100	54-125	54-107	71-89
Lipids (g)	1.3-3.0	1.3-2.6	1.7-2.1	-	-	-
Amino Acids (g)*	1.5-3.5	1.5-3.0	2.0-2.5	1.5-3.5	1.5-3.0	2.0-2.5
Glucose (g)	6-14	6-12	8-10	6-14	6-12	8-10
Energy (kcal)	43-100	43-86	57-72	30-70	30-60	40-50
Electrolytes (mmol)						
Sodium	1.2-2.8	1.2-2.4	1.6-2.0	1.2-2.8	1.2-2.4	1.6-2.0
Potassium	1.0-2.5	1.1-2.1	1.4-1.8	1.1-2.5	1.1-2.1	1.4-1.8
Chloride	1.0-2.5	1.1-2.1	1.4-1.8	1.1-2.5	1.1-2.1	1.4-1.8
Calcium	0.7-1.6	0.7-1.4	0.9-1.1	0.7-1.6	0.7-1.4	0.9-1.1
Phosphorous	0.7-1.6	0.7-1.4	0.9-1.1	0.6-1.4	0.6-1.2	0.8-1.0
Magnesium	0.1-0.2	0.1-0.2	0.1	0.1-0.2	0.1-0.2	0.1

* Dose-limiting component: total dosage must be within the recommended limit of amino acids

Pedismof Neonate and Infant should be infused continuously over 20 to 24 hours in neonates and infants. Cyclic infusion (administration in less than 20-24 hours) may be introduced in stable infants. The same bag should not be infused for longer than 24 hours.

Maximum infusion rate

The recommended maximum infusion rate for the activated three chamber bag and two chamber bag are shown in Table 2. The infusion rate is determined by dividing the volume by the duration of the infusion.

Table 2 Recommended Maximum Infusion Rate over 20 Hours for Activated two chamber bag and three chamber bag (units/kg/h) by component

	Activated three chamber bag			Activated two chamber bag		
	Preterm neonates	**Term neonates**	**Infants**	**Preterm neonates**	**Term neonates**	**Infants**
Fluid (mL)	7.00	6.00	5.00	6.25	5.35	4.45
Lipids (g)	0.15	0.13	0.11	-	-	-
Amino Acids (g)*	0.18	0.15	0.13	0.18	0.15	0.13
Glucose (g)	0.70	0.60	0.50	0.70	0.60	0.50

* Rate-limiting component: maximum rate must not exceed recommended rate of amino acids

Treatment duration

Treatment with parenteral nutrition may be continued for as long as is required by the patient's clinical conditions.

Compatibility

Compatibility data are available with the named branded products Peditrace Novum, Vitalipid N Infant, Soluvit N and Glycophos in defined amounts, and generics of electrolytes in defined concentrations. When making electrolyte additions, the amounts already present in the bag should be taken into account to meet the clinical needs of the patient. Generated data supports additions to the activated bag according to the summary tables below:

Table 3. Three chamber bag compatibility range stable for 7 days at 2-8°C followed by either 48 hours at room temperature (20-25°C) or for 24 hours at 37 ± 2°C

	Units	Maximal total contents
Pedismof Neonate and Infant bag size	ml	500
Additive		**Volume**
Peditrace Novum	ml	0 – 8.5
Soluvit N	vial	0 – 0.5
Vitalipid N Infant	ml	0 - 30
Electrolyte limits[1]		
Sodium	mmol/l	≤ 100
Potassium	mmol/l	≤ 100
Magnesium	mmol/l	≤ 5
Phosphate organic (Glycophos)	mmol/l	≤ 30

1. *includes amounts from all products*

Table 4. Two chamber bag compatibility range stable for 7 days at 2-8°C followed by either 48 hours at room temperature (20-25°C) or for 24 hours at 37 ± 2°C

	Units	Maximal total contents
Pedismof Neonate and Infant bag size, glucose and amino	ml	446.4
Additive		**Volume**
Peditrace Novum	ml	0 – 8.5
Soluvit N, reconstitued with water for injection	vial	0 – 0.4
Electrolyte limits[1]		
Sodium	mmol/l	≤ 100
Potassium	mmol/l	≤ 100
Magnesium	mmol/l	≤ 5
Phosphate organic (Glycophos)	mmol/l	≤ 30

1. *includes amounts from all products*

Note: These tables are intended to indicate compatibility. They are not a dosing guideline.
For branded products, before prescribing refer to national approved prescribing information.

Compatibility with further additives and the storage time of different admixtures will be available upon request.

If solutions are added to Pedismof, the osmolarity of the *final* mixture should be considered to choose the appropriate route of infusion (central or peripheral). The osmolarity can be calculated by summing up the products of osmolarity and volume for the individual solutions, divided by the sum of volumes of all solutions mixed (total volume in litre):

$$final\ Osm. = \frac{(Osm.\ Pedismof\ x\ Vol) + (Osm.\ \ Sol\ 1\ x\ Vol) + (Osm.\ Sol\ 2\ x\ Vol) + \cdots}{total\ Vol\ (Pedismof + Sol\ 1 + Sol\ 2 + \cdots)}$$

Osm. = osmolarity [milliosmols per litre, mOsm/L]
Vol = volume in litre [L]
Sol 1 = solution number 1 added
Sol 2 = solution number 2 added
… = further solutions to be added, if applicable
x = multiplied

Additions should be made aseptically.

Pedismof Neonate and Infant should not be given simultaneously with blood in the same infusion set due to the risk of pseudoagglutination.

Shelf-life after mixing the chambers of the bag
In-use stability of the mixed two and three chamber bags has been demonstrated for up to 7 days at 2-8°C followed by 48 hours at room temperature (20-25°C), including duration of administration. From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage time and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless mixing has taken place in controlled and validated aseptic conditions.

Shelf life after mixing with additives
In-use stability of the mixed two and three chamber bag with additives has been demonstrated for up to 7 days at 2-8°C followed by either 48 hours at room temperature (20-25°C) or for 24 hours at 37 ± 2°C, including duration of administration. From a microbiological point of view, the product should be used immediately when additions have been made. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C, unless addition of supplements has taken place in controlled and validated aseptic conditions.

Light protection
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.

What Pedismof Neonate and Infant contains

Table 5. Active ingredients

Active ingredients (g)	**Activated two chamber bag (446 ml)**	**Activated three chamber bag (500 ml)**
Amino acid chamber		
L-Alanine	1.2	1.2
L-Arginine	0.79	0.79
L-Aspartic acid	0.79	0.79
L-Cysteine	0.19	0.19

L-Glutamic acid	1.4	1.4
Glycine	0.40	0.40
L-Histidine	0.40	0.40
L-Isoleucine	0.59	0.59
L-Leucine	1.3	1.3
Lysine monohydrate *corresponding to* L-Lysine	1.1	1.1
L-Methionine	0.25	0.25
L-Phenylalanine	0.52	0.52
L-Proline	1.1	1.1
L-Serine	0.73	0.73
Taurine	0.057	0.057
L-Threonine	0.69	0.69
L-Tryptophan	0.27	0.27
L-Tyrosine	0.096	0.096
L-Valine	0.69	0.69
Calcium gluconate monohydrate *corresponding to Calcium gluconate*	2.5	2.5
Sodium glycerophosphate (hydrate) *corresponding to* Sodium glycerophosphate	1.1	1.1
Magnesium sulphate heptahydrate *corresponding to* Magnesium sulphate	0.086	0.086
Potassium chloride	0.67	0.67
Glucose chamber		
Glucose monohydrate *corresponding to Glucose*	50.0	50.0
Lipid chamber		
Soya-bean oil, refined	0	3.2
Medium-chain triglycerides	0	3.2
Olive oil, refined	0	2.7
Fish oil, rich in omega-3-acids	0	1.6

Corresponding to:

	Activated two chamber bag		**Activated three chamber bag**	
Per volume unit (ml)	**446**	**100**	**500**	**100**
Amino acids (g)	13	2.8	13	2.5
Nitrogen (g)	2.0	0.45	2.0	0.40
Electrolytes (mmol)				
- sodium[1]	9.9	2.2	10	2.0
- potassium	8.9	2.0	8.9	1.8
- magnesium	0.71	0.16	0.71	0.14
- calcium	5.7	1.3	5.7	1.1
- phosphate[1]	4.9	1.1	5.7	1.1
- sulphate	0.71	0.16	0.71	0.14
- chloride	8.9	2.0	8.9	1.8
- acetate	2.5	0.56	2.5	0.50
Carbohydrates (g)				
- Glucose (anhydrous)	50.0	11.2	50.0	10.0
Lipids (g)	0	0	11	2.1

Energy content (kcal)				
- total (approx.)	250	56.0	358	71.6
- non protein (approx.)	200	44.8	308	61.5
Osmolarity (approx.) [2]	970 mOsm/L	970 mOsm/L	890 mOsm/L	890 mOsm/L
pH	5.7	5.7	5.7	5.7

[1]Contribution from the lipid emulsion and the amino acid solution.
[2] Calculated theoretical value

The other ingredients are:

Excipients	Amino Acid Chamber	Glucose Chamber	Lipid Chamber
all-*rac*- α -Tocopherol (E307)	-	-	X
Glacial acetic acid * (E260)	X	-	-
Glycerol (E422)	-	-	X
Purified egg phospholipids	-	-	X
Sodium Hydroxide* (E524)	-	-	X
Sodium oleate	-	-	X
Water for injection	X	X	X

* for pH adjustment