PACKAGE LEAFLET

Package leaflet: Information for the patient

Pedismof 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 is and what it is used for

Pedismof is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (term), infants, children and adolescents. 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 contains amino acids (components used to build proteins), electrolytes (salts), glucose (carbohydrates) and lipids (fat).

Pedismof is presented in the form of a three chamber plastic bag. The respective chambers contain:
- a 6.5% amino acid solution with electrolytes
- a 18.2% 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 must only be used under medical supervision.

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

Your child should not be given Pedismof, 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 (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 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
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 (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.

Pregnancy and breast-feeding
If your child is pregnant or breast-feeding, may be pregnant or is planning to have a baby, ask your child´s doctor for advice before your child is given this medicine.

Your child will only be given Pedismof during pregnancy or breast-feeding, if the doctor considers treatment to be necessary. Breastfeeding is possible during treatment with this medicine.

3. How Pedismof is given

Your child's doctor will decide on the dose depending on the body weight and function of your child. Pedismof 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 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 is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (term), infants, children and adolescents. 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.

If your child is given too much Pedismof
It is unlikely that your child will receive too much medicine as Pedismof 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 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. 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 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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store Pedismof

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 contains
See information intended for health care professional at the end of the package leaflet.

What Pedismof looks like and contents of the pack
Pedismof, 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 18.2%	Lipid emulsion 20 % (SMOFlipid)
1000 ml	319 ml	573 ml	108 ml
1500 ml	479 ml	859 ml	162 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 1000 ml
4 x 1500 ml

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
[To be completed nationally]

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

This medicine is authorised in the Member States of the European Economic Area under the following names:
[To be completed nationally]

This leaflet was last revised in 26 June 2025.
<[To be completed nationally]>

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The following information is intended for healthcare professionals only:

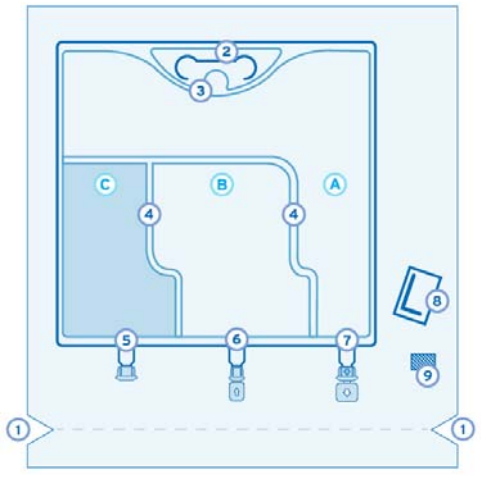
Special precautions for disposal and other handling
No additions to the bag should be made without first checking the compatibility (see table 4 and 5 below).

For single use only.

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

Instructions for use

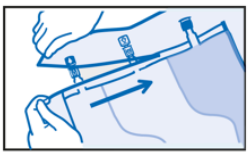
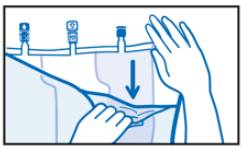
Schematic overview of the bag

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.

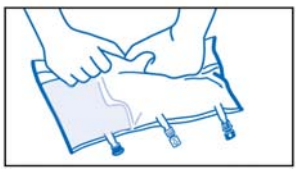
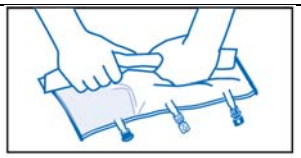
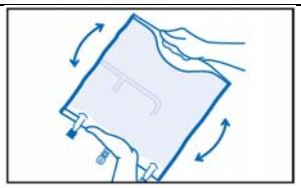
2. Removal of overpouch

• 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.	

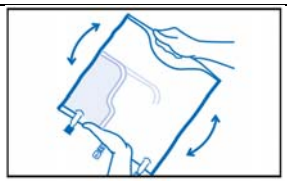
3. Mixing

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.

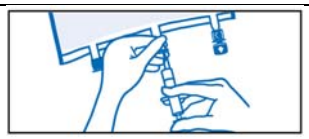
3.1 Activation of the 3 chambers (mixing of 3 solutions by breaking two peelable seals)

• 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.*	

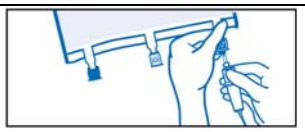
3.2 Activation of the 2 chambers (mixing of 2 solutions by breaking the peelable seal between the amino acid and glucose chamber)

• 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)

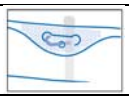
• Place the bag on a flat surface again. Shortly before injecting additives, break off the white additive port cap with the arrow pointing toward the bag.	
• Hold the base of the additive port. Insert the needle through the centre of the additive port's septum and inject the additives (with known compatibility). • 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 severely malnourished patients may result in refeeding syndrome, which is characterized by the intracellular shift of potassium, phosphorus, and magnesium as patients become anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, careful and slow initiation of PN 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 children below 2 years of age, Pedismof 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.

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 should be monitored and adjusted to meet the clinical 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 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 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 section 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, 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.

In neonates, the recommended dosage is up to 120 mL/kg/d for the activated three chamber bag and up to 107 mL/kg/d for the activated two chamber bag (Table 1). The dose can be increased gradually over the first days. The maximum recommended daily dosage of 120 mL/kg for the activated three chamber bag and 107 mL/kg for the activated two chamber bag should not be exceeded.

In infants, the recommended dosage is 80 to 100 mL/kg/d for the activated three chamber bag and 71 to 89 mL/kg/d for the activated two chamber bag (Table 1. The dose can be increased gradually over the first days. The maximum recommended daily dosage of 100 mL/kg for the activated three chamber bag and 89 mL/kg for the activated two chamber bag should not be exceeded.

In children, the recommended dosage is 60 to 80 mL/kg/d for the activated three chamber bag and 54 to 71 mL/kg/d for the activated two chamber bag (Table 1). The dose can be increased gradually over the first days. The maximum recommended daily dosage of 80 mL/kg for the activated three chamber bag and 71 mL/kg for the activated two chamber bag should not be exceeded.

In adolescents, the recommended dosage is 40 to 50 mL/kg/d for the activated three chamber bag and 36 to 45 mL/kg/d for the activated two chamber bag (Table 1). The dose can be increased gradually

over the first days. The maximum recommended daily dosage of 50 mL/kg for the activated three chamber bag and 45 mL/kg for the activated two chamber bag should not be exceeded.

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

	Term neonates		Infants		Children		Adolescents	
	Three chamber bag	Two chamber bag	Three chamber bag	Two chamber bag	Three chamber bag	Two chamber bag	Three chamber bag	Two chamber bag
Fluid (mL)	≤120	≤107	80-100	71-89	60-80	54-71	40-50	36-45
Lipids (g)	≤2.6	-	1.8-2.2	-	1.3-1.7	-	0.9-1.1	-
Amino Acids (g)*	≤2.5	≤2.5	1.7-2.1	1.7-2.1	1.3-1.7	1.3-1.7	0.8-1.0	0.8-1.0
Glucose (g)	≤12.5	≤12.5	8.3-10.4	8.3-10.4	6.3-8.3	6.3-8.3	4.2-5.2	4.2-5.2
Energy (kcal)	≤86	≤60	58-72	40-50	43-57	30-40	30-36	20-25
Electrolytes (mmol)								
Sodium	≤2.2	≤2.2	1.5-1.9	1.5-1.8	1.1-1.5	1.1-1.5	0.7-0.9	0.7-0.9
Potassium	≤2.0	≤2.0	1.3-1.7	1.3-1.7	1.0-1.3	1.0-1.3	0.7-0.8	0.7-0.8
Chloride	≤2.0	≤2.0	1.3-1.7	1.3-1.7	1.0-1.3	1.0-1.3	0.7-0.8	0.7-0.8
Calcium	≤0.8	≤0.8	0.5-0.7	0.5-0.7	0.4-0.5	0.4-0.5	0.3	0.3
Phosphate	≤1.0	≤0.8	0.6-0.8	0.5-0.7	0.5-0.7	0.4-0.5	0.4	0.3
Magnesium	≤0.2	≤0.2	0.1-0.2	0.1-0.2	0.1	0.1	0.1	0.1

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

In neonates and infants, Pedismof should be infused continuously over 20 to 24 hours. Cyclic infusion (administration in less than 20-24 hours) may be introduced in stable infants. In children and adolescents, the infusion should be preferably 10 to 12 hours as cyclic infusion. 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 for neonates and infants in Table 2 and for children and adolescents in * Rate-limiting component: maximum rate must not exceed recommended rate of amino acids

Table 3. The infusion rate is determined by dividing the volume by the duration of the infusion. The infusion rate should be controlled using an electronic flow-regulating device (pump, syringe driver).

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

	Activated three chamber bag		Activated two chamber bag	
	Term neonates	Infants	Term neonates	Infants
Fluid (mL)	6.0	5.0	5.35	4.45
Lipids (g)	0.13	0.11	-	-
Amino Acids (g)*	0.13	0.11	0.13	0.11
Glucose (g)	0.63	0.52	0.63	0.52

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

Table 3 Recommended Maximum Infusion Rate over 10 Hours for Activated three chamber bag and two chamber bag in Children and Adolescents (units/kg/h) by Component

	Activated three chamber bag		Activated two chamber bag	
	Children	**Adolescents**	**Children**	**Adolescents**
Fluid (mL)	8.00	5.00	7.10	4.50
Lipids (g)	0.17	0.11	-	-
Amino Acids (g)*	0.17	0.10	0.17	0.10
Glucose (g)	0.83	0.52	0.83	0.52

* 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 4 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 bag size	ml	1000	1500
Additive		**Volume**	
Peditrace Novum	ml	0 – 8.5	0 – 12.8
Soluvit N	vial	0 - 1	0 – 1.5
Vitalipid N Infant	ml	0 - 60	0 - 90
Electrolyte limits[1]			
Sodium	mmol/l	≤ 100	≤ 100
Potassium	mmol/l	≤ 100	≤ 100
Magnesium	mmol/l	≤ 5	≤ 5
Phosphate organic (Glycophos)	mmol/l	≤ 30	≤ 30

1. *includes amounts from all products*

Table 5 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 bag size, glucose and amino acid chambers only	ml	891.7	1337.5
Additive		**Volume**	
Peditrace Novum	ml	0 – 8.5	0 – 12.8
Soluvit N, reconstitued with water for injection	vial	0 – 0.9	0 – 1.4
Electrolyte limits[1]			
Sodium	mmol/l	≤ 100	≤ 100
Potassium	mmol/l	≤ 100	≤ 100
Magnesium	mmol/l	≤ 5	≤ 5
Phosphate organic (Glycophos)	mmol/l	≤ 30	≤ 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

Addition should be made aseptically.

Pedismof 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 times 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 bags 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 contains

Table 6. Active ingredients

Active ingredients (g)	**Activated two chamber bag**		**Activated three chamber bag**	
Volume (ml)	**892**	**1338**	**1000**	**1500**
Amino acid chamber				
L-Alanine	2.0	3.0	2.0	3.0
L-Arginine	1.3	2.0	1.3	2.0
L-Aspartic acid	1.3	2.0	1.3	2.0
L-Cysteine	0.32	0.48	0.32	0.48
L-Glutamic acid	2.3	3.4	2.3	3.4
Glycine	0.67	1.0	0.67	1.0
L-Histidine	0.67	1.0	0.67	1.0
L-Isoleucine	0.99	1.5	0.99	1.5
L-Leucine	2.2	3.4	2.2	3.4
Lysine monohydrate *corresponding to* L-Lysine	1.8	2.7	1.8	2.7
L-Methionine	0.42	0.62	0.42	0.62
L-Phenylalanine	0.86	1.3	0.86	1.3
L-Proline	1.8	2.7	1.8	2.7
L-Serine	1.2	1.8	1.2	1.8
Taurine	0.096	0.14	0.096	0.14
L-Threonine	1.2	1.7	1.2	1.7
L-Tryptophan	0.45	0.67	0.45	0.67
Tyrosin	0.16	0.24	0.16	0.24
L-Valine	1.2	1.7	1.2	1.7
Calcium gluconate monohydrate *corresponding to* *Calcium gluconate*	2.9	4.3	2.9	4.3
Sodium glycerophosphate (hydrate) *corresponding to* Sodium glycerophosphate	1.5	2.2	1.5	2.2

Magnesium sulphate heptahydrate *corresponding to* Magnesium sulphate	0.20	0.30	0.20	0.30
Potassium chloride	1.2	1.9	1.2	1.9
Sodium acetate trihydrate *corresponding to* Sodium acetate	0.40	0.59	0.40	0.59
Glucose chamber				
Glucose monohydrate *corresponding to Glucose*	104	156	104	156
Lipid chamber				
Soya-bean oil, refined	0	0	6.5	9.8
Medium-chain triglycerides	0	0	6.5	9.8
Olive oil, refined	0	0	5.4	8.1
Fish oil, rich in omega-3-acids	0	0	3.3	4.9

Corresponding to:

	Activated two chamber bag			**Activated three chamber bag**		
Per volume unit (ml)	**892**	**1338**	**100**	**1000**	**1500**	**100**
Amino acids (g)	21	31	2.3	21	31	2.1
Nitrogen (g)	3.3	5.0	0.37	3.3	5.0	0.33
Electrolytes (mmol)						
- sodium[1]	18	27	2.0	19	28	1.9
- potassium	17	25	1.9	17	25	1.7
- magnesium	1.7	2.5	0.19	1.7	2.5	0.17
- calcium	6.7	10	0.75	6.7	10	0.67
- phosphate[1]	6.7	10	0.75	8.3	13	0.83
- sulphate	1.7	2.5	0.19	1.7	2.5	0.17
- chloride	17	25	1.9	17	25	1.7
- acetate	9.0	14	1.0	9.0	14	0.90
Carbohydrates (g)						
- Glucose (anhydrous)	104	156	11.7	104	156	10.4
Lipids (g)	-	-	-	22	33	2.2
Energy content (kcal)						
- total (approx.)	500	750	56.1	718	1077	71.8
- non protein (approx.)	417	625	46.7	634	951	63.4
Osmolarity (approx.)[2]	940 mOsm/L	940 mOsm/L	940 mOsm/L	860 mOsm/L	860 mOsm/L	860 mOsm/L
pH	5.6	5.6	5.6	5.6	5.6	5.6

[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