

Package leaflet: Information for the user

Paedisol solution for infusion

(Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, and glucose monohydrate)

Read all of this leaflet carefully before you start using 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 doctor, pharmacist or nurse.
- If you get any side effects, talk to your 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 Paedisol is and what it is used for
2. What you need to know before you use Paedisol
3. How to use Paedisol
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1. What Paedisol is and what it is used for

Paedisol is a solution for intravenous infusion (into a vein). It contains minerals called electrolytes that affect the amount of water in your body and other important processes. It also contains carbohydrates.

Paedisol is used in new-born babies (0 to ≤ 28 days), babies (28 days to ≤ 2 years), children (2 to ≤ 12 years) and adolescents (12 to ≤ 14 years) as follows:

- It helps to restore fluid levels and the normal electrolyte (salt) balance after an operation. It also contains glucose which provides a source of energy.
- It acts as a plasma volume substitute that is used to restore the blood volume.
- It helps to restore fluid and electrolyte deficiencies.
- It is used as a carrier solution for other electrolytes and medicinal products.

2. What you need to know before you use Paedisol

Do not use Paedisol:

- if your child is allergic (hypersensitive) to sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetate, glucose or any of the other ingredients of this medicine (listed in section 6).
- for premature neonates and neonates (≤ 28 days of age): Your child must not receive a certain antibiotic called ceftriaxone as a drip into a vein concomitantly with this medicine
- if your child has excess water in its body (hyperhydration)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before your child is given Paedisol if your child has:

- less acid in the body than normal (metabolic alkalosis)
- abnormally high level of sugar in blood (hyperglycaemia)
- abnormally low level of potassium in the blood (hypokalaemia)
- abnormally high level of sodium in the blood (hypernatraemia)
- abnormally high level of chloride in its blood (hyperchloraemia)
- kidney failure or diminished kidney function
- been treated with a certain antibiotic named ceftriaxone; it must not be mixed or given simultaneously with any calcium containing solutions given by a drip into the vein. Your doctor knows this and will not give them together even via different infusion lines or different infusion sites.
 - However, in children older than 28 days your doctor may give calcium and ceftriaxone sequentially one after another if infusion lines at different sites are used or if the infusion lines are replaced or were thoroughly flushed with physiological salt solution between the infusions to avoid precipitation. If you or your child suffer from low blood volume your doctor will avoid giving calcium and ceftriaxone sequentially.

While your child is given this medicine, its serum electrolyte levels, water balance, blood glucose levels and the acid-base status will be checked from time to time.

Caution is required in children, particularly in newborn babies and babies, when administering this medicine. This is because lactic acidosis (increased lactic acid in the body) can occur. To be taken into consideration with children who are born with problems utilising lactate.

Other medicines and Paedisol

Tell your doctor or pharmacist if your child is using, has recently used or might use any other medicines.

- Concomitant use with ceftriaxone (an antibiotic), when given intravenously, is not recommended (see section Warnings and precautions).

Pregnancy and breast-feeding

Paedisol is intended for use in children (under 14 years of age) only

3. How to use Paedisol

Your doctor or other healthcare professional will give your child this medicine through an infusion into a vein (intravenous drip).

Dosage

The amount of the medicine that your child will be given, will be determined by your doctor and will depend on your child's age, weight, clinical condition and other therapy your child is receiving. Thus, its individual requirements of fluid, electrolytes and energy will be taken into account. Your doctor will decide on the correct dose for your child to receive.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you are given more Paedisol than you should

As your child will be given this medicine by a doctor or other healthcare professional, your child

is unlikely to be given the wrong dose.

An overdose may lead to excess fluid in the body (hyperhydration) and high blood sugar (hyperglycaemia).

The therapy to normalise your child's condition will be determined by your doctor. It may include stopping of the infusion, monitoring your child's blood salt level and administration of suitable medicines to treat your child's symptoms (e.g. diuretics, insulin).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Not known (frequency cannot be estimated from the available data)

Local site reactions due to the administration technique:

- fever (febrile response)
- infection at the site of infusion
- irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused
- the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring

Reporting of side effects

If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2,

Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail:

medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paedisol

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

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

This medicinal product does not require any special storage conditions.

Use only if the solution is clear, without visible particles and if the container is undamaged.

Use immediately after first opening. 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°C - 8°C, unless opening and storage have taken place in controlled and validated aseptic conditions.

When combined with other solutions for infusion, the general current requirements for the mixture of medicinal products must be considered (e.g. aseptic conditions, compatibility and thorough mixture).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paedisol contains

Each ml of Paedisol solution for infusion contains:

Sodium chloride	6.429 mg
Potassium chloride	0.298 mg
Calcium chloride dihydrate	0.147 mg
Magnesium chloride hexahydrate	0.203 mg
Sodium acetate trihydrate	4.082 mg
Glucose monohydrate	11.0 mg
(Equivalent to Glucose)	10.0 mg)

The other ingredients are hydrochloric acid 37 % (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Paedisol looks like and contents of the pack

Paedisol is a clear, colourless to slightly yellow aqueous solution for infusion.

Paedisol is available in 100 ml, 250 ml and 500 ml low-density polyethylene bottles as primary packaging closed with a polyethylene or polyethylene/polypropylene cap containing a polyisoprene stopper.

Pack sizes:

40 x 100 ml bottles

20 x 250 ml bottles

10 x 500 ml bottles

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi Deutschland GmbH

Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

Fresenius Kabi Polska Sp. z o. o.
ul. Sienkiewicza 25
PL – 99-300 Kutno
Poland

This medicine is authorized in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	ELO-MEL paediatric Infusionslösung
Belgium	Kidialyte oplossing voor infusie/solution pour perfusion/Infusionslösung
Bulgaria	Бенелайт инфузионен разтвор Benelyte solution for infusion
Croatia	Benelyte otopina za infuzij
Czech Republic	Benelyte
Denmark	Benelyte
Estonia	Benelyte
Germany	Benelyte Infusionslösung
Finland	Benelyte Infusioneste, liuos
France	Pedialyte, solution pour perfusion
Hungary	Benelyte oldatos infúzió
Ireland	Paedisol solution for infusion Benelyte šķīdums infūzijām
Lithuania	Benelyte infuzinis tirpalas
Luxembourg	Benelyte Infusionslösung
Netherlands	Kidialyte oplossing voor infusie
Norway	Benelyte
Poland	Benelyte
Portugal	Benelyte
Romania	Benelyte soluție perfuzabilă
Slovenia	Benelyte raztopina za infundiranje
Slovakia	Benelyte
Spain	Benelyte solución para perfusión
Sweden	Benelyte
United Kingdom (Northern Ireland)	Minorsol solution for infusion

**This leaflet was last revised in
August 2023**

The following information is intended for medical or healthcare professionals only

Please see the Summary of Product Characteristics for more information.

Posology

The dosage in perioperative intravenous infusion therapy depends on the fluid, electrolyte, and glucose requirements:

During the first hour e.g. 10 – 20 ml/kg/hr, and thereafter for regulation of the infusion rate according to basic and correction requirements with monitoring of relevant cardiovascular and laboratory parameters.

For fluid requirements the following reference values apply:

Neonates (0 to ≤ 28 days), infants (28 days to ≤ 1 year):
100 – 140 ml/kg body mass/day

Infants aged 1 to ≤ 2 years:
80 – 120 ml/kg body mass/day

Children aged 2 to ≤ 5 years:
80 – 100 ml/kg body mass/day

Children aged 5 to ≤ 10 years:
60 – 80 ml/kg body mass/day

Children aged 10 to ≤ 12 years and adolescents aged 12 to ≤ 14 years:
50 – 70 ml/kg body mass/day

For short-term intravascular volume replacement the dosage should be determined individually according to the fluid needs.

For the treatment of isotonic dehydration in the paediatric population the rate of infusion and the daily dose should be determined individually according to the nature and severity of the electrolyte and water imbalance by monitoring the relevant cardiovascular and laboratory parameters.

If Paedisol is used in combination with other solutions for infusion the current guidelines on the total fluid supply for the relevant age group should be considered upon dosage calculation.

The individual water, electrolyte, and carbohydrate requirements should be calculated and replaced accordingly; in particular, pre-term and underweight neonates, but also in all other exceptional therapeutic situations. Balancing needs to be more exact the pre-term, younger, and underweight the patient is.

Method of administration

For intravenous use.

Duration of administration

The duration of administration depends on the patients fluid and electrolyte requirements.

Incompatibilities

Incompatibility of the medicinal product to be added to Paedisol must be assessed before addition. In general, it can be stated that the following medicinal products (groups) must not be mixed with Paedisol:

- Medicinal products that might form hardly soluble precipitations with the constituents of the solution. (The preparation contains Ca^{2+} ions. Precipitation may occur with the addition of inorganic phosphate, hydrogen carbonate/ carbonate or oxalate.)
- Medicinal products that are not stable in an acid pH-range or do not exhibit optimum efficacy or decompose
- Paedisol must not be mixed with other medicinal products or solutions for parenteral nutrition for which compatibility has not been tested.
- Solutions for infusion that contain glucose must not be administered simultaneously through the same infusion equipment with blood because of the possibility of pseudo-agglutination.