

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Primene 10% Solution for Infusion

Read all of this leaflet carefully before you are 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 the doctor or nurse.
- If you get any side effects, talk to the doctor or nurse. This includes any possible side effects not listed in this leaflet, see section 4.

In this leaflet:

- 1 What Primene is and what it is used for
- 2 What you need to know before your child is given Primene
- 3 How Primene is given
- 4 Possible side effects
- 5 How Primene is stored
- 6 Contents of the pack and other information

Throughout this leaflet Primene 10% Solution for Infusion will be called Primene.

1 What Primene is and what it is used for

Primene is a sterile solution which contains:

- amino acids – these are the building blocks which your body uses to make proteins

Primene is used in Children, infants and the newborn at term or born prematurely to give your child food (nutrition) straight into the blood, when your child cannot take enough food by his or her mouth.

The doctor will check your body has all the nutrition that it needs for good health. If necessary, your child may also have a vitamins (such as folic Acid), minerals, fatty acids (the building blocks of fats), electrolytes (salts) and sugar solutions (such as glucose) at the same time as Primene.

2 What you need to know before your child is given Primene

Primene must not be given to your child if:

- your child is allergic (hypersensitive) to any of the ingredients of Primene (see section 6)
- Your child's body has problems using the building blocks of proteins.

Your child will not be given Primene if any of the above applies.

Warnings and precautions

Talk to the doctor or nurse before Primene is given to your child.

- When used in neonates and children below 2 years of age, the solution (in bottles and administration sets) should be protected from light exposure until administration is completed. Exposure of Primene to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure.
- Your child will have regular blood and urine tests while being given Primene. This will make sure that your child is getting the right amount of solution and if necessary your child will be given other treatments
- Your child will be monitored more closely if you have kidney, heart, liver or breathing problems. Please tell your doctor if your child has any problems with his or her kidneys, heart, liver or breathing.
- If any abnormal signs or symptoms of an allergic reaction develop, such as fever, chills, skin rashes or difficulty in breathing, excessive sweating, nausea or headache, tell the doctor or the nurse: the infusion will be stopped immediately.
- Primene can cause the formation of small particles in your blood. If your child starts to have difficulty breathing or feel short of breath, tell the doctor or the nurse: the infusion will be stopped immediately and your child may need other treatment.
- Certain medications and illnesses can increase the risk of developing infection or sepsis (bacteria in the blood). There is a particular risk of infection or sepsis when a tube (intravenous catheter) is placed in your child's vein. The doctor will carefully watch your child for any signs of infection. Using aseptic "germ free" techniques when placing and maintaining the catheter and when making the nutritional formula can reduce the risk of infection.
- If your child is severely malnourished such that they need to receive feeding through a vein, it is recommended that parenteral nutrition is started slowly and carefully.

- Amino acid solutions can increase the level of ammonia or nitrogen-containing compounds in your child's blood. The doctor will check your child's blood tests for this.
- The doctor should also be aware of severe conditions affecting how your child's body handles fluid, sugars, fats, proteins or salt (metabolic disorders). These conditions will be corrected before your child is given Primene.
- your child will not have Primene through the same tubes and equipment used for any blood transfusion.

Use with other medicines

There are no known problems when Primene is used with other medicines.

Pregnancy and breast-feeding

If your child is pregnant, think she might be pregnant or is breast-feeding, tell the doctor. They will decide if she can be given Primene.

3 How Primene is given

The doctor will decide how much Primene your child should be given. It will depend on:

- age and weight
- what his or her body needs
- why he or she is being given it.
- **the usual daily dose** is 15 to 35 ml of Primene per kilogram of body weight.
- these are the recommended amounts to have each day, but your child may be given more or less
- Primene is given as an infusion into a large vein in your child's chest (called the vena cava). When mixed with other solutions it may be given into a vein in your child's arm. The solution is slowly given to your child at a rate which will not be more than 0.05 ml per kg per minute.
- When used in neonates and children below 2 years of age, the solution (in bottles and administration sets) should be protected from light exposure until administration is completed (see section 2).

If your child is given too much

The doctor will give your child Primene so it is unlikely that your child will be given too much. If you are worried that your child has had too much, tell the doctor or nurse.

If the dose given is too high or the infusion too fast, your child may have an increased volume of circulating blood, your child's blood may become too acidic or the nitrogen content in your child's blood and urine may increase.

Symptoms may include nausea, vomiting, shivering, confusion and rapid heart rate. In such situations, the infusion must be stopped immediately.

The doctor will decide if additional actions are required.

To prevent these events from occurring, the doctor will regularly monitor your child's condition and test your child's blood levels during treatment.

4 Possible side effects

Like all medicines, Primene 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 right away. The tests the doctor will perform while your child is taking the medicine minimise the risk of side effects.

If any abnormal signs or symptoms of an allergic reaction develop, such as abnormally low or high blood pressure, appearance of a blue or purple coloration of the skin, abnormally high heart rate, breathing difficulties, joint pain, muscle pain, vomiting, nausea, skin rashes, raised body temperature, excessive sweating, chills, and shivering, the infusion will be stopped immediately.

The following side effects have been reported with similar products:

- High blood level of ammonia and nitrogen-containing compounds
- Anaphylactic reactions, a serious allergic shock reaction that is rapid in onset and if not treated can be life-threatening.
- Impairment of liver functions, abnormal blood test for the liver function
- Inflammation of the gall bladder, the presence of gallstones in the gallbladder
- Increase in the acidity of the blood
- Formation of small particles blocking lung blood vessels
- Vein inflammation at infusion site, venous irritation, pain, warmth, swelling and induration
- Severe local reactions can occur in case of leakage of the infusion fluid in the tissues surrounding the infusion site: death of skin tissue, blistering, swelling, scarring, skin discoloration.

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

Turn over leaflet for further information.

You can also report side effects directly to the Medicines and Healthcare products Regulatory Agency via the Yellow Card Scheme:

www.mhra.gov.uk/yellowcard

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

5 How Primene is stored

Keep the medicine out of the sight and reach of children when not being administered.

When used in neonates and children below 2 years, the solution (in bottles and administration sets) should be protected from light exposure until administration is completed.

Primene should be stored as follows:

Do not store above 25°C and protect it from light.

Do not use Primene after the expiry date which is stated on the label after Exp. The expiry date means the last day of that month.

Partly used containers should not be used again. Any left over solution should be thrown away safely by a healthcare professional. All equipment will be thrown away safely by a healthcare professional after use.

6 Contents of the pack and other information

What Primene contains

- The active substances are L-Isoleucine 6.70 g, L-Leucine 10.00 g, L-Valine 7.60 g, L-Lysine 11.00 g, L-Methionine 2.40 g, L-Phenylalanine 4.20 g, L-Threonine 3.70 g, L-Tryptophan 2.00 g, L-Arginine 8.40 g, L-Histidine 3.80 g, L-Alanine 8.00 g, L-Aspartic Acid 6.00 g, L-Cysteine 1.89 g, L-Glutamic Acid 10.00 g, Glycine 4.00 g, L-Proline 3.00 g, L-Serine 4.00 g, L-Tyrosine 0.45 g, L-Ornithine Hydrochloride 3.18 g, Taurine 0.6 g in 1000 ml of solution.
- The other ingredients are sterile water (called 'water for injections') and L-Malic acid.

What Primene looks like and the contents of the pack

Primene is a solution for infusion. It is a clear sterile solution. It is available in glass bottles containing 100 ml, 125 ml, 200 ml, 250 ml, 500 ml, 1,000 ml or 2,000 ml of solution.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:

Baxter Healthcare Ltd

Caxton Way
Thetford
Norfolk
IP24 3SE
United Kingdom

Send all enquiries to this address.

Primene is made at the following place:

Bieffe Medital S.p.A.
Via Nuova Provinciale
I-23034 Grosotto
Italy

This leaflet was last revised 11/2019

For information about Primene or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: 01635 206345.

Baxter and Primene are trademarks of Baxter International Inc.

