

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

### **Primene 10% Solution for Infusion** Amino Acid Intravenous Infusion

**Read all of this leaflet carefully before your child is given this medicine because it contains important information for your child**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor or nurse.
- If your child gets any side effects talk to the doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is 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 your child will be given Primene
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. The amino acids in Primene are listed in section 6.

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.

Your doctor will check your child has all the nutrition that they need for good health. If necessary, your child may also have 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 this medicine (listed in section 6).
- Your child's body has a problem s 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.

Your doctor will make sure that:

- 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 has 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 they 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. See Section 4.
- 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 you start 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.
- you will not have Primene through the same tubes and equipment used for any blood transfusion.

## **Other medicines and Primene**

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

## **Pregnancy and breast-feeding**

Primene is intended for use in children. The doctor will decide if Primene can be given to patients who are pregnant, think they might be pregnant or are breast-feeding.

### **3. How your child will be given Primene**

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 are being given it.
- the usual daily dose is 15 to 30 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 the chest (called the vena cava) or into a vein in the arm. When mixed with other solutions your doctor will decide which vein to use depending on the strength of the mixture. The solution is slowly given to your child at a rate which will not be more than 0.05 ml per kg per minute.
  - Your child will not be given more than 30 millilitres for every kilogram of their bodyweight in a day.
  - 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 more Primene than they should**

Your 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, oedema of the face or the eyelids, 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.

- Amino acid solutions, like Primene, can increase the possibility of folate deficiency (Vit B9).

The following side effects have been reported with similar products:

- High blood level of ammonia and nitrogen-containing compounds
- Serious allergic shock reaction
- 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.

### **Reporting of Side Effects**

If your child gets any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## **5. How Primene is stored**

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

When used in infants less than 2 years of age, 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 from light. Do not refrigerate or freeze.

Do not use this medicine if you notice the container is leaking, or if solution is cloudy or is in any other way suspicious.

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.

For single use only. Discard any unused contents.

Partly used containers should not be used again. Any leftover 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 or 250 ml of solution.

### **Marketing Authorisation Holder and Manufacturers**

The Marketing Authorisation holder is:

#### **Baxter Holding B.V.**

Kobaltweg 49,  
3542CE Utrecht,  
Netherlands

Send all enquiries to this address.

Primene is manufactured by:

#### **Bieffe Medital S.p.A.**

Via Nuova Provinciale  
I-23034 Grosotto  
Italy

**This leaflet was last revised 09/2019**

**For information about Primene or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0) 1635 206345.**