

## **PRIMENE 10%**

### **Amino Acids Intravenous (IV) Infusion**

#### **Consumer Medicine Information**

##### **What is in this leaflet?**

This leaflet answers some common questions about **Primene® 10% amino acids IV infusion**. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks against the benefit to your baby by having **Primene 10%** for his/her treatment.

This leaflet does not take the place of talking to your doctor, pharmacist, or other health professionals. If you have any concerns about being administered this medicine to your baby, ask your doctor or pharmacist.

Keep this leaflet with the medicine, as you may need to read it again.

##### **What Primene 10% is used for and how it works**

The brand name of the medicine for your baby is **Primene 10%**. It is a mixture of amino acids, a building block of proteins. This medicine contains a well-balanced protein composition intended as a source for nutritional support for growth in premature babies in particular. In the early life, a rapid growth of tissues and organs, such as liver and kidney requires essential nutrients. Under a normal condition these are provided by breast milk. However, premature babies and infants who cannot be fed orally should be fed by infusion of a nutritional supplement, such as **Primene 10%**.

##### **What should you know before the use of Primene 10%**

###### **Primene 10% should not be given to a baby, infant, premature infant if:**

- a baby has had an allergic reaction to any component of **Primene 10%** listed in the Ingredients section of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, peeling of the skin, swelling of the face, lips or tongue, which may cause difficulty swallowing or shortness of breath.
- a baby is born with a congenital abnormality with metabolism of one or more amino acids listed in the Ingredients section of this leaflet.
- a baby is suffering from liver or uncontrolled kidney problem.
- the expiry date printed on the pack is overdue.

###### **You must tell your doctor if:**

- your baby is allergic to anything.
- your baby has any other health problems.

## **How is Primene infusion given?**

### **How much is given:**

Your doctor will decide how much Primene 10% will be infused to your baby, which normally depends on the weight and condition of your baby.

### **How it is given:**

The infusion of Primene 10% to premature babies requires a special delivery system. It is usually given together with an appropriate source of energy for the needs of your baby, as a continuous and slow rate of infusion for up to 24 hours. The needle is normally placed on a large vein either on a central or peripheral blood vessel.

### **In case of overdose**

Your doctor and nurse know what action to take if overdose does occur, which is very rare with such this medication. However, in the unlikely event, your healthcare provider will take an appropriate action and discontinue the Primene 10% infusion. The symptoms of overdose are the same as those listed below under Side Effects.

## **While your baby is having Primene 10%**

Discuss with your baby's doctor the progress made by your baby after the treatment, whether any complication has occurred, especially during the first few days of therapy. Frequent clinical evaluation and laboratory tests may be required. As Primene 10% is normally given in a hospital, your nurse healthcare provider will take records of the progress and unexpected adverse reactions.

## **Side effects**

Premature babies are at risk of much complication. Serious abnormality may occur with or without Primene 10%. There is a chance of unintentional infections. As with all other preparations similar to Primene 10%, inflammation of the veins on the site of injection may occur.

If any of the following happen, the Primene 10% infusion must be discontinued and the doctor on duty to be informed immediately:

- swelling of the face, lips, mouth or difficulty in breathing
- yellowing of the skin and eyes, also called jaundice.

## **Storage conditions**

The hospital will store unopened Primene 10% below 25 °C, and protected from light.

## **Product descriptions**

### **What Primene 10% looks like**

It is a clear colourless to slightly yellow solution of amino acids without electrolytes presented in a glass bottle. Primene 10% is intended for use as a nutrition supplement in neonates and infants given by slow infusion.

## Ingredients:

The active and inactive components of Primene 10% formulated in one litre are listed in the following table 1.

**Table 1: each one litre of Primene 10% (w/v) infusion contains**

<u>Active constituents</u>	Primene 10% [ g ]
L- Lysine	11.00
L- Glutamic acid	10.00
L- Leucine	10.00
L- Arginine	8.40
L- Alanine	8.00
L- Valine	7.60
L- Isoleucine	6.70
L- Aspartic acid	6.00
L- Phenylalanine	4.20
Glycine	4.00
L- Serine	4.00
L- Histidine	3.80
L- Threonine	3.70
L- Ornithine Hydrochloride	3.18 (2.49 as a base)
L- Proline	3.00
L- Methionine	2.40
L- Tryptophan	2.00
L- Cysteine	1.89
Taurine	0.60
L- Tyrosine	0.45

### Other constituents

L- Malic acid q.s. to make pH  $5.5 \leq 3.2$

Water for injection q.s. to 1000mL

Primene 10% contains no preservative and must be used within 24 hours of preparation with other components included in the infusion.

### Manufacturer and Sponsor

Primene 10% IV infusion is made in France by Baxter/Clintec Parenteral,  
and supplied in Australia by:

Baxter Healthcare Pty Ltd,  
1 Baxter Drive  
Old Toongabbie, NSW 2146  
Australia.

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