

PRIMENE 10%

Amino Acids Intravenous Infusion

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about PRIMENE 10% amino acids IV infusion [PRIMENE 10%]. It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist, or other health professionals.

All medicines have risks and benefits. Your doctor has weighed the risks of your baby being given PRIMENE 10% against the benefits they expect it will have for your baby.

If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet.

You may need to read it again.

What PRIMENE 10% is used for

PRIMENE 10% is a mixture of amino acids, a building block of proteins. This medicine contains a well-balanced composition of protein 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 the liver and kidney requires essential nutrients. Under a normal condition these are provided by breast milk. However, premature babies, infants who cannot be fed orally, they should be fed by infusion of a nutritional supplement, such as PRIMENE 10%.

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 at the end of this leaflet or its container components. 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 suffering from liver or kidney problems.
- The expiry date printed on the pack is overdue.

Tell your doctor if:

- Your baby is allergic to anything
- Your baby has any other health problems including infections.

How PRIMENE 10% is given?

How much is given:

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

How is it 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, by your doctor or specially trained nurse.

If your baby is given too much (overdose)

The doctor or nurse administering PRIMENE 10% infusion has had experience in the use of this sort of medicine, so it is unlikely that your baby will receive too much.

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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following:

- Swelling of the face, lips, mouth
- Difficulty in breathing.
- Swelling of eyelid.
- Yellowing of the skin and eyes, also called jaundice.
- Blistering, swelling, scarring, skin discoloration at the infusion site

Product description

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

PRIMENE 10% contains the following ingredients:

Active ingredients

- L – Lysine
- L – Glutamic acid
- L – Leucine
- L – Arginine
- L – Alanine
- L – Valine
- L – Isoleucine

- L – Aspartic acid
- L – Phenylalanine
- Glycine
- L – Serine
- L – Histidine
- L – Threonine
- L – Ornithine Hydrochloride
- L – Proline
- L – Methionine
- L – Tryptophan
- L – Cysteine
- Taurine
- L – Tyrosine

Inactive ingredients

- L – Malic acid
- Water for injection

Storage Conditions

PRIMENE 10% will be stored in the pharmacy or in the hospital ward. PRIMENE 10% is to be stored below 25°C and away from light.

Sponsor

Baxter Healthcare Pty Ltd
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Old Toongabbie NSW 2146
Australia

PRIMENE 10% (AUST R 79618) is available in 100 mL and 250 mL packs.

Date of preparation:

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