

## APPROVED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S3**

#### **AMINOVEN INFANT 10 %** Solution for infusion

Isoleucine, leucine, lysine acetate, methionine, phenylalanine, threonine, tryptophan, valine, arginine, histidine, glycine, alanine, proline, serine, taurine, tyrosine, cysteine, malic acid.

Sugar free.

#### **Read all of this leaflet carefully before your child receives AMINOVEN INFANT 10 %**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

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

1. What AMINOVEN INFANT 10 % is and what it is used for
2. What you need to know before your child is given AMINOVEN INFANT 10 %
3. How your child is given AMINOVEN INFANT 10 %
4. Possible side effects
5. How to store AMINOVEN INFANT 10 %
6. Contents of the pack and other information

#### **1. What AMINOVEN INFANT 10 % is and what it is used for**

AMINOVEN INFANT 10 % is a nitrogen source for partial parenteral nutrition therapy of infants and young children when oral or enteral nutrition is impossible, insufficient or contraindicated.

Together with required amounts of carbohydrates and fat as energy sources as well as vitamins, electrolytes and trace elements, this solution may serve for total parenteral nutrition.

## **2. What you need to know before your child is given AMINOVEN INFANT 10 %**

**AMINOVEN INFANT 10 % should not be administered to your child if he/she:**

- is hypersensitive (allergic) to any of the active ingredients (see complete list in section 6) or any of the other ingredients of AMINOVEN INFANT 10 % (listed in section 6)
- has a condition where your body has problems using proteins or amino acids
- has metabolic acidosis (the acid levels of your body fluids and tissues become too high)
- has reduced kidney function and is not on dialysis or another form of blood filtration treatment
- has seriously reduced liver function
- has fluid retention
- suffers from shock
- has hypoxia (low levels of oxygen)
- has a decompensated heart failure.

### **Warnings and precautions**

Special care should be taken with AMINOVEN INFANT 10 %.

Frequent evaluation and determination of the following laboratory values should be recommended for monitoring parenteral nutrition in infants: urea-nitrogen, ammonia, electrolytes, glucose and triglycerides (when a fat emulsion is administered), acid-base and fluid balance, liver enzymes and serum osmolality.

Infusion via peripheral veins in general can cause irritation of the vein wall and thrombophlebitis.

To minimise the risk of vein irritation, daily inspections of the insertion site are recommended.

When used in infants and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of AMINOVEN INFANT 10 % 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.

### **Other medicines and AMINOVEN INFANT 10 %**

Always tell your healthcare provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

### **AMINOVEN INFANT 10 %with food and drink**

Not applicable.

### **Pregnancy and breastfeeding**

Not applicable. AMINOVEN INFANT 10 % is intended for infants and young children.

### **Driving and using machinery**

Not applicable.

## **3. How your child is given AMINOVEN INFANT 10 %**

You will not be expected to give your child AMINOVEN INFANT 10 %. It will be given to him/her by a person who is qualified to do so.

### **Maximum infusion rate:**

Up to 0,1 g amino acids/kg body weight/hour = 1,0 ml /kg body weight/hour

### **Maximum daily dose:**

- at the age of 1 year:

1,5 – 2,5 g amino acids/kg body weight = 15 – 25 ml per kg body weight

- at the age of 2 – 5 years:

1,5 g amino acids/kg body weight = 15 ml per kg body weight

- at the age of 6 – 14 years:

1,0 g amino acids/kg body weight = 10 ml per kg body weight

The solution is administered as long as parenteral nutrition is required.

AMINOVEN INFANT 10 % should be used with sterile transfer equipment immediately after opening. Any unused solution should be discarded.

Only clear, particle-free solutions in undamaged containers should be used.

For long-term parenteral nutrition with AMINOVEN INFANT 10 % essential fatty acids, vitamins and trace elements should be substituted.

#### **If your child receives more AMINOVEN INFANT 10 % than he/she should**

Since a healthcare provider will administer AMINOVEN INFANT 10 %, he/she will control the dosage. However, in the event of overdosage your child's doctor will manage the overdosage.

The effects of an overdose may include nausea, vomiting and shivering. If your child experiences these symptoms or believes that he/she has received too much AMINOVEN INFANT 10 %, inform your child's doctor or nurse immediately.

#### **4. Possible side effects**

AMINOVEN INFANT 10 % can have side effects.

Not all side effects reported for AMINOVEN INFANT 10 % are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while receiving AMINOVEN INFANT 10 %, please consult his/her doctor, pharmacist or other healthcare provider for advice.

None known when correctly administered.

If any of the following happens, tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to AMINOVEN INFANT 10 %.

Tell your doctor if you notice any of the following side effects:

***Frequent:***

Thrombophlebitis and irritation of the cell wall especially when administered peripherally.

***Frequency unknown:***

Too rapid infusion may lead to nausea and vomiting.

Gastric hyperacidity, which should be treated with H<sub>2</sub> antagonists.

Too rapid infusion may lead to shivering attacks.

Renal losses with subsequent amino acid imbalances may occur if the infusion is too rapid.

Where the contraindications, precautions and dosage recommendations are adhered to, adverse reactions are unknown.

If you notice any side effects not mentioned in this leaflet, please inform your child's doctor or pharmacist.

## Reporting of side effects

If your child gets side effects, talk to his/her doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AMINOVEN INFANT 10 %.

## 5. How to store AMINOVEN INFANT 10 %

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze. Protect from light.

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

The solution must not be used after the expiry date shown on the label. Any solution remaining after treatment should be disposed of via approved hospital procedures.

## 6. Contents of the pack and other information

### What AMINOVEN INFANT 10 % contains

- The active substances are:

Each 1 000 ml of AMINOVEN INFANT 10 % contains:

Isoleucine                      8,00 g

Leucine                            13,00 g

Lysine acetate                 12,00 g

(= Lysine 8,51 g)

Methionine                      3,12 g

Phenylalanine	3,75 g
Threonine	4,40 g
Tryptophan	2,01 g
Valine	9,00 g
Arginine	7,50 g
Histidine	4,76 g
Glycine	4,15 g
Alanine	9,30 g
Proline	9,71 g
Serine	7,67 g
Taurine	0,40 g
N-acetyl-L-Tyrosine	5,176 g
(= L-tyrosine 4,20 g)	
N-acetyl-L-cysteine	0,70 g
(= L-cysteine 0,52 g)	
Malic acid	2,62 g

- The other ingredients are:

Water for injection.

### **What AMINOVEN INFANT 10 % looks like and contents of the pack**

A clear solution in 100 ml, 250 ml and 1 000 ml glass bottles.

AMINOVEN INFANT 10 % is available in 100 ml, 250 ml and 1 000 ml clear glass bottles, sealed with a rubber closure and an aluminium cap, packed in an outer carton in the following package sizes:

10 x 100 ml

10 x 250 ml

1 x 1 000 ml

10 x 1 000 ml

Not all pack sizes may be marketed.

**Holder of the certificate of registration**

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**Access to the corresponding Professional Information**

The professional information will be printed and packed with the product.