NAME OF THE MEDICINE

Arginine Hydrochloride

The molecular weight of the compound is 210.7 and the CAS registry number is 1119-34-2. The molecular formula is $C_6H_{14}N_4O_2 \cdot HCl$.

**Structural Formula:**

\[
\text{H}_2\text{N}\text{-}\text{H}\text{-}\text{H}\text{-}\text{N}^+\text{-}\text{C}_2\text{H}_4\text{O}_2\text{H}^+\cdot \text{HCl}
\]

DESCRIPTION

**ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION** 15 g in 25 mL contains arginine hydrochloride 600 mg/mL in water for injections to 25 mL.

Arginine is an aliphatic amino acid which is essential for infant growth. It is used as a dietary supplement.

PHARMACOLOGY

Arginine is an isomer of the amino acid arginine, which is an essential amino acid found in the body. Arginine is generally absorbed from the intestinal tract, and processed by the liver. Arginine is an important constituent of the urea cycle, which enables the body to safely store and excrete ammonia.

Arginine is considered to be a normal metabolite in animals and man.

INDICATIONS

Arginine stimulates the release of growth hormone by the pituitary gland and may be used instead of, or in addition to, other tests such as insulin-induced hypoglycaemia, for the evaluation of growth disorders; false positive and false negative results are relatively common and evaluation therefore should not be made on the basis of a single arginine test.

Arginine is used as an acidifying agent in severe metabolic alkalosis.

Arginine is used in some conditions accompanied by hyperammonaemia stemming from inborn errors of the urea cycle, particularly where there is a severe deficiency of ornithine carbamoyl transferase or carbamoyl phosphate synthetase, where respiratory alkalosis is present.

CONTRAINDICATIONS

**ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION** is contraindicated in:

- Patients who are highly allergic.
- In patients hypersensitive to arginine or who have severe acidosis.
- In patients with hypotension or any defects or diseases related to nitric oxide production.
PRODUCT INFORMATION
Arginine Hydrochloride 60%
Concentrated Injection
15 g in 25 mL

PRECAUTIONS

Anti-histamine medication should be available during treatment, in the event of an allergic reaction.

Patient blood pressure should be monitored during use and for 24 hours following cessation of intravenous administration due the possibility of hypotension.

Use with Caution

ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION should be used with caution in patients with severe liver disease and moderate renal insufficiency. Elevated plasma-potassium concentrations have been reported in uraemic patients and arginine should therefore be administered with caution to patients with renal disease or anuria. ARGinine HYDROCHLORIDE 60% CONCENTRATED INJECTION should be administered cautiously to patients with electrolyte disturbances as its high chloride content could lead to the development of hyperchloraemic acidosis.

Use in Pregnancy

ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION belongs to pregnancy Category B1- Drugs which have been taken by a limited number of pregnant women and women of child bearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals have not shown evidence of increased occurrence of fetal damage.

Use in Lactation

Although arginine passes through breast milk, it is not considered to affect the nursing child negatively. However, caution is advised when breast feeding.

Carcinogenicity

Long term animal studies have not been performed to evaluate the carcinogenic potential, the mutagenic potential or the effect on fertility of intravenously administered ARGinine HYDROCHLORIDE 60% CONCENTRATED INJECTION

INTERACTIONS WITH OTHER MEDICINES

Arginine has been known to interact with spironolactone.

ADVERSE EFFECTS

Nausea, vomiting, flushing, headache, numbness and local venous irritation may occur if arginine solutions are infused too rapidly.

Rare Adverse Reactions: Hypotension, anaphylactic reactions, severe allergic reactions and severe hyperkalaemia have all been reported, but occurrences are extremely rare.

DOSAGE AND ADMINISTRATION

ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION is compatible for dilution with either Sodium Chloride 0.9% or Glucose 5%. It should be diluted before use to make a concentration of arginine hydrochloride 10%. The resulting infusion solution should be given over 30 minutes.

The usual dose is:
Adults: 30 g of arginine hydrochloride.
PRODUCT INFORMATION
Arginine Hydrochloride 60%
Concentrated Injection
15 g in 25 mL

Children: 500 mg of arginine hydrochloride per kilogram of bodyweight.

In severe metabolic alkalosis the intravenous dose (in grams) is calculated by multiplying the desired decrease in plasma bicarbonate concentration (mmol. per litre) by the patient’s body weight in kilogram and then dividing by a factor of 9.6.

OVERDOSAGE

An overdosage may cause a transient metabolic acidosis with hyperventilation. The acidosis can generally be compensated and the base deficit will return to normal following completion of the infusion. If the condition persists, the deficit should be determined and corrected by a calculated dose of an alkalosing agent. Hypotension may develop due to stimulation of nitric oxide production.

In Australia, contact the Poisons Information Centre on 13 11 26 for further advice on overdose management.

PRESENTATION AND STORAGE CONDITIONS

ARGININE HYDROCHLORIDE 60% CONCENTRATED INJECTION 15 g in 25 mL contains 600 mg/mL arginine hydrochloride in water for injections to 25 mL. The product is filled in a 50 mL glass vial and sold in cartons of 10. Store below 30°C.

AUST R 22934

Phebra product code- INJ162

NAME AND ADDRESS OF THE SPONSOR

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POISON SCHEDULE OF THE MEDICINE

Unscheduled

Date of first inclusion in the Australian Register of Therapeutic Goods: 14 October 1991
Date of most recent amendment: 18 December 2013

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