INSTRUCTIONS FOR PREPARATION PACKAGE INSERT
ARGININE HYDROCHLORIDE 60% INJECTION (arginine hydrochloride)
concentrated injection for infusion 15 g in 25 mL

This product is an unapproved therapeutic good in Australia. It is manufactured in a TGA approved pharmaceutical manufacturing facility in Australia and is provided under Schedule 5A – subregulation 12(1A) of the Therapeutic Goods Act and Regulations. The product is supplied under contract between a public or private hospital or public institution and the licensed manufacturer in Australia in accordance with a specified formulation.

Approval for use is required from the hospital pharmacist and/or drug committee as appropriate. Informed consent should be obtained in accordance with good medical practice where applicable and practicable. Records of the use of the product should be fully detailed and include dose, route of administration, duration of treatment, clinical, biochemical, haematological and immunological monitoring as appropriate. Adverse events and reactions must be reported to Phebra Pty Ltd and the TGA.

The responsibility for the use of this product remains with the prescriber and the institution. The following product information has not been evaluated or approved by the Therapeutic Goods Administration. Physicians should consult the medical literature for the most recent advice concerning the appropriate dose, route of administration, warnings and adverse effects.

NAME OF THE MEDICINE

Arginine hydrochloride

DOSAGE FORM

Concentrated injection for intravenous infusion.

METHOD OF PREPARATION

Arginine Hydrochloride 60% 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.

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.

STORAGE CONDITIONS AFTER PREPARATION

Store below 30°C. Do not freeze.

SPONSOR

Phebra Pty Ltd
17-19 Orion Road
Lane Cove West
NSW 2066
Australia
Ph 1800 720 020

VERSION/DATE OF REVISION

Version 1.0 – 20 March 2026