Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Arginine Hydrochloride Injection 60%. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Arginine Hydrochloride Injection 60% against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Arginine Hydrochloride Injection 60% is used for

Arginine Hydrochloride Injection 60% is used to treat:

- severe metabolic alkalosis where the pH of the blood is too high
- disorders in the urea cycle present at birth

Arginine Hydrochloride Injection 60% can also be used to stimulate the release of human growth hormone which can then be used as part of a test to evaluate growth disorders.

Ask your doctor if you have any questions about why Arginine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given Arginine Hydrochloride Injection

When you must not be given it

You must not be given Arginine Hydrochloride Injection 60% if you have an allergy to Arginine Hydrochloride.

Some of the symptoms of an allergic reaction may include:

- · shortness of breath
- · wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash itching or hives on the skin.

You should not be given this medicine if you have too much acid in your blood.

This may be indicated by an increased rate of breathing.

You must not be given this medicine if you have low blood pressure.

You should not be given this medicine if you have problems metabolising Arginine.

That is diseases related to nitric acid production.

You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate is present.

The solution is normally a clear, colourless liquid.

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If you are given this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- · severe liver disease
- · kidney disease
- anuria (no production or passing of urine)
- unusual amount of salt in the body.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Arginine Hydrochloride Injection 60%.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket, health food shop, herbalist or naturopath.

Some medicines and Arginine Hydrochloride Injection 60% may interfere with each other. These include:

 Spironolactone, a diuretic used to treat heart disease or oedema.

This medicine may be affected by Arginine, or may affect how well it works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Arginine.

How Arginine Hydrochloride Injection 60% is given

Arginine Hydrochloride Injection 60% must only be given by a doctor or nurse.

It is usually diluted and given as a slow infusion into a vein.

Your doctor will decide what dose of Arginine Hydrochloride Injection 60% you will receive and for how long you will receive it. This depends on your medical condition and other factors, such as your weight.

If you are given too much (overdose)

Arginine Hydrochloride Injection 60% must only be given by a doctor or nurse so an overdose is not likely to occur.

Symptoms of an overdose usually disappear after treatment with this medicine has finished.

Symptoms may include:

- · rapid breathing
- faintness, dizziness or light-headedness
- numbness around the mouth, fingertips or toes
- cramping in the hands and fingers.

Immediately contact your doctor or nurse or go to Accident and Emergency at the nearest hospital if you notice symptoms of an overdose.

While you are being given Arginine Hydrochloride Injection 60%

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Arginine Hydrochloride Injection 60%.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Arginine affects you.

This medicine may cause dizziness or lightheadedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get out of bed or chairs, will help your body get used to changes in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Arginine Hydrochloride Injection 60%.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea or vomiting
- flushing
 - headache
- numbness
- irritation at the site of the injection.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor or nurse immediately, or go to accident or emergency at your local hospital:

- · dizziness or light headedness
- rash, itching or hives on the skin
- swelling of face, lips, tongue or other parts of the body
- shortness of breath
- · wheezing or troubled breathing

· changes in heart rate or chest pain.

The above list includes some very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Some side effects not listed above may also occur in some people.

Some of the side effects (for example high levels of potassium in the blood) can only be found when your doctor does tests from time to time to check your progress.

After being given Arginine Hydrochloride Injection 60%

Storage

Arginine Hydrochloride Injection 60% will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a cool dry place where the temperature stays below 30°C.

Arginine Hydrochloride Injection 60% will be opened for use on you. It will be used only once and then it will be discarded. It will never be stored after it is opened or used for more than one person.

Product description

What it looks like

Arginine Hydrochloride Injection 60% is a clear, colourless solution in a clear glass vial sealed with a grey rubber stopper and aluminium seal with a white plastic flip off cap in packs of 10.

25mL of the product is supplied in 50mL vials.

Ingredients

Arginine Hydrochloride Injection 60% contains 0.6g/mL of Arginine Hydrochloride in Water for Injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine, dyes or any preservatives.

Manufacturer

Arginine Hydrochloride Injection 60% is made in Australia by

Phebra Pty Ltd

19 Orion Road Lane Cove West, NSW 2066 Australia



AUST R 22934

Phebra Product Code: INJ162

This leaflet was amended December 2013.