PROLASTIN® C LIQUID

PROLASTIN C LIQUID Alpha-1-proteinase inhibitor (human) 500 mg solution for injection for intravenous infusion vial
PROLASTIN C LIQUID Alpha-1-proteinase inhibitor (human) 1000 mg solution for injection for intravenous infusion vial
PROLASTIN C LIQUID Alpha-1-proteinase inhibitor (human) 4000 mg solution for injection for intravenous infusion vial

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using PROLASTIN® C (prō-'lăs-tĭn) LIQUID.

This leaflet answers some common questions about PROLASTIN® C LIQUID, a prescription medicine. 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 using PROLASTIN® C LIQUID against the benefits they expect it will have for you.

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

Keep this leaflet with you. You may need to read it again.

What Prolastin® C Liquid is used for

PROLASTIN® C LIQUID is used to treat Alpha-1-proteinase inhibitor deficiency. This is a genetic disorder. It is characterised by very low amounts of your own Alpha-1-proteinase inhibitor protein in your lungs. Some patients develop a serious lung disease called emphysema.

PROLASTIN® C LIQUID contains human Alpha-1-proteinase inhibitor manufactured from blood products. You take PROLASTIN® C LIQUID to boost Alpha-1-proteinase inhibitor in your bloodstream and lungs.

One of the reasons your lungs have been damaged is because you lack enough of Alpha-1-proteinase inhibitor. Other causes include smoking and infections. Alpha-1-proteinase inhibitor inhibits enzymes that break down lung tissue. Be aware that there are no medical studies in people to prove that taking PROLASTIN® C LIQUID over a long period of time will stop or slow down the symptoms of emphysema.

Before you use Prolastin® C Liquid

When you must not use it

Do not use PROLASTIN® C LIQUID if you know you lack immunoglobulin A (IgA) in your bloodstream and your body has made its own antibodies against IgA. You could have a bad allergic reaction to PROLASTIN® C LIQUID because it contains trace amounts of IgA.

Smoking is not recommended during your treatment with PROLASTIN® C LIQUID.

If you are not sure whether you should use PROLASTIN® C LIQUID, talk to your doctor.

Your doctor should not administer PROLASTIN® C LIQUID if the carton seal has been broken.

Before you start to use it

Tell your doctor if:

- You are pregnant or intend to become pregnant. It is not known whether PROLASTIN® C LIQUID is harmful to an unborn baby when given to a pregnant woman.
- You are breastfeeding. Many medicines are excreted into the human breast milk.
- You do not tolerate medicines made from blood.
- You are concerned that your child may be treated with PROLASTIN® C LIQUID. The safety and effectiveness of PROLASTIN® C LIQUID in children have not been established.
- You are a smoker as the effectiveness of PROLASTIN® C LIQUID in smokers has not been established.

If you have not told your doctor about any of the above, tell your doctor before you are treated with PROLASTIN® C LIQUID.

Your body may not tolerate PROLASTIN® C LIQUID if you have the very rare condition of "IgA deficiency" and your body has already made its own antibodies against immunoglobulin A (IgA). If your doctor suspects that you are experiencing an allergic or anaphylactic reaction during administration of PROLASTIN® C LIQUID, your doctor must immediately discontinue the infusion.

Special safety warning

When medicines are made from human plasma, certain measures are put in place to prevent infections from viruses or the Creutzfeldt-Jakob disease (CJD) agent from being passed on to patients. These include

- Carefully selecting plasma donors to make sure those at risk of carrying infections are excluded.
- Testing of each donation and pools of plasma for signs of virus or virus infections.
- Including steps in the processing of the plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human plasma are administered, the possibility of passing on infection cannot be totally excluded. This applies to any unknown or emerging viruses or other types of infections.

Discuss the risks and benefits of this medicine with your doctor before using it.

Talk to your doctor if you become sick with a virus infection. Your doctor or you may want to report the infection to Grifols Australia Pty Ltd 1800 339 479.

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 or health food shop. You should also tell any health professional who is prescribing a new medicine for you that you are using PROLASTIN® C LIQUID.

Your doctor has more information on medicines to be careful with or avoid while using PROLASTIN® C LIQUID. Interactions with other medicines are not known.

How to use Prolastin® C Liquid

How much to use

Your doctor will decide the amount of PROLASTIN® C LIQUID that is right for you. A standard dose is 60 milligrams of PROLASTIN® C LIQUID for every 1 kilogram of body weight. PROLASTIN® C LIQUID is administered into a vein with fluid. This is usually done in a health care facility. You will need to be observed for at least 20 minutes after the infusion.

When to use it

Your doctor will determine when your treatments should be given. The standard schedule is weekly. The infusion takes approximately 15 minutes.

How long to use it

You will use PROLASTIN® C LIQUID weekly until your doctor tells you otherwise.

If you forget to use it

If you miss a scheduled infusion of PROLASTIN® C LIQUID, talk to your doctor about rescheduling.

While you are using Prolastin® C Liquid

Things you must do

If you are about to be started on any new medicine tell your doctor that you are using PROLASTIN® C LIQUID.

Things you must not do

Do not give PROLASTIN® C LIQUID to anyone else, even if they have the same condition as you.

Things to be careful of

No effects on ability to drive and use machines have been observed with PROLASTIN® C LIQUID.

In case of overdose

If you use too much (overdose)

There have been no reported cases of overdose for PROLASTIN® C LIQUID. No data are available concerning overdose in humans.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much PROLASTIN® C LIQUID.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor as soon as possible if you do not feel well after being treated with PROLASTIN® C LIQUID.

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 known adverse effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if any of the following side effects happen during or soon after the infusion.

- Headache
- Dizziness
- Fatigue

- Shortness of breath (dyspnoea)
- Hives (urticaria) or rash

Occasionally, you may experience:

- Chills
- Chest discomfort or pain
- Out of sorts feeling (malaise)
- Itching (pruritus)
- Allergic or anaphylactic type reactions including shock
- Influenza-like illness

Rarely, you may experience:

- Racing heartbeat (tachycardia)

There is a possibility that your body could react to PROLASTIN® C LIQUID. Allergic reactions to PROLASTIN® C LIQUID have occurred. If you go into shock, your doctor will treat you by following standard guidelines for shock therapy.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other side effects or if any of the above side effects get serious.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Prolastin® C Liquid

Storage

Your doctor must store PROLASTIN® C LIQUID unopened vials refrigerated at 2°C to 8°C with no more than 1 month at room temperatures (up to 25°C) after which the product must be used or immediately discarded. PROLASTIN® C LIQUID should never be stored in a freezer. Your doctor must use PROLASTIN® C LIQUID on or before the expiry date stamped on the label. Do not use after the expiration date.

Your doctor must never use PROLASTIN® C LIQUID that was ever frozen, is cloudy, or discoloured. **The solution is clear or slightly opalescent, colourless or pale yellow or pale green or pale brown.** The solution may have a few particles in it.

All medicines, including PROLASTIN® C LIQUID, must be kept out of reach of children.

Disposal

Your doctor will dispose of any unused or expired medicine or medical waste in accordance with local requirements.

Medicines should not be disposed of into wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

PROLASTIN® C LIQUID is a clear or slightly opalescent, colourless or pale yellow or pale green or pale brown solution in a glass vial.

Ingredients

Active ingredient:

- Alpha-1-proteinase inhibitor

Inactive ingredients:

- Alanine
- monobasic sodium phosphate monohydrate
- water for injections

PROLASTIN® C LIQUID is sterile and does not contain an antimicrobial preservative.

Sponsor details

Grifols Australia Pty Ltd
Unit 5/80 Fairbank Road, Clayton South, VIC 3169
Australia

Australian Registration Number

PROLASTIN® C LIQUID

Alpha-1-proteinase inhibitor (human) 500 mg solution for injection for intravenous infusion vial: AUST R 371334

Alpha-1-proteinase inhibitor (human)1000 mg solution for injection for intravenous infusion vial: AUST R 305253

Alpha-1-proteinase inhibitor (human) 4000 mg solution for injection for intravenous infusion vial: AUST R 371339

Date of preparation

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