Biological Therapies Sodium Ascorbate Solution

Injection for Intravenous Infusion 30 g in 100 mL, 15 g in 100mL, 15 g in 50 mL, 45 g in 500 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sodium Ascorbate Solution Injection for Intravenous Infusion.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving Sodium Ascorbate Solution Injection against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Sodium Ascorbate Solution Injection is used for

Sodium Ascorbate Solution Injection contains the active ingredient sodium ascorbate (Vitamin C).

Sodium Ascorbate Solution Injection may be prescribed if you have a diagnosed Vitamin C deficiency and are unable to absorb sufficient Vitamin C when taking it by mouth. Your doctor may have prescribed Sodium Ascorbate Solution Injection for another reason. Ask your doctor if you have any questions about why Sodium Ascorbate Solution Injection has been prescribed for you.

Sodium Ascorbate Solution Injection is not addictive.

Before you have Sodium Ascorbate Solution Injection

When you must not use it:

Do not have Sodium Ascorbate Solution Injection given if:

 You have a known allergy to Vitamin C

If you have had an allergic reaction to vitamin C before, you may be allergic to Sodium Ascorbate Solution Injection.

 You have kidney disease or kidney stones

There have been a few cases where injected vitamin C has made kidney disease worse.

- The packaging is torn or shows signs of tampering
- The expiry date (Exp.) printed on the pack has passed
 If you have this medicine after the expiry date, it may not work and it may be harmful to you.

If you are not sure whether you should have Sodium Ascorbate

Solution Injection given, talk to your doctor.

Before you have it injected:

If you have any of the following medical illnesses or conditions, you must tell your doctor. Your doctor will discuss the risks and benefits of using Sodium Ascorbate Solution Injection if you have any of these illnesses or conditions.

- Tell your doctor if you have had an allergy to any of the ingredients in this medicine, any other medicines or any other substances, such as foods, preservatives or dyes.
- Tell your doctor if you have kidney disease or kidney stones.
- Tell your doctor if you have haemochromatosis, thalassaemia, polycythemia, leukaemia or sideroblastic anaemia due to enhanced absorption of dietary iron.
- Tell your doctor if you have high uric acidity.
- Tell your doctor if you have high sodium levels.
- Tell your doctor if you have Sickle Cell Anaemia.
- Tell your doctor if you have G6PD (Glucose-6-phosphate dehydrogenase Deficiency.
- Tell your doctor if you are pregnant or breastfeeding

Your doctor will discuss the risks and benefits of using Sodium

Ascorbate Solution Injection while pregnant or breastfeeding

If you have not told your doctor about any allergies you might have, tell them before you have Sodium Ascorbate Solution Injection given.

If 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.

Some medicines and Sodium Ascorbate Solution Injection may interfere with each other. These include:

- Aspirin
- Iron Oral Supplements
- · Alcohol
- Amphetamine or other antidepressants
- Dicoumarol or Warfarin, medicines used to prevent blood clots
- Ethinyloestradiol, a medicine used in oral contraceptives
- Desferrioxamine, a medicine used to lower iron stores
- Isoprenaline, a medicine used as a heart medication
- Mexiletine, a medicine used as a heart medication and for nerve pain
- Barbiturates or primidone, medicines used as sedatives
- Fluphenazine, a medicine used in psychiatric treatment.

These medicines may be affected by Sodium Ascorbate Solution Injection, or may affect how well it works.

Your doctor or pharmacist will advise you and decide whether or not to give you Sodium Ascorbate Solution Injection.

How Sodium Ascorbate Solution Injection is given

Sodium Ascorbate Solution Injection will be infused (slowly injected) intravenously (into a vein) by your doctor. Your doctor will decide the best way to do this.

How much is given:

Your doctor will tell you how much Sodium Ascorbate Solution Injection will need to be given.

How long to use it:

Each person will respond differently to Sodium Ascorbate Solution Injection.

Your doctor will advise you about the length of treatment with Sodium Ascorbate Solution Injection.

If you forget an appointment or need to change an appointment:

You will need to make another appointment as soon as possible.

If you are not sure what to do, contact your doctor or pharmacist as soon as possible.

If too much is given (overdose):

Your doctor should be the only person to inject Sodium Ascorbate Solution Injection.

But if you think that you or anyone else may have been given too much Sodium Ascorbate Solution Injection immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are being treated with Sodium Ascorbate Solution Injection

Things you must do:

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with Sodium Ascorbate Solution Injection.

Tell your doctor if you feel that giving Sodium Ascorbate Solution Injection is not helping your condition.

Be sure to keep all appointments with your doctor so that your progress can be checked.

Things you must not do:

Do not inject Sodium Ascorbate Solution Injection yourself.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

Things to be careful of:

Each person will respond differently while being given Sodium Ascorbate Solution Injection.

It is common to become dehydrated or feel thirsty while being given Sodium Ascorbate Solution Injection. You should drink plenty of water during and after your injection.

Sometimes people feel dizzy or faint during an injection of Sodium Ascorbate Solution Injection. If this happens, immediately tell the person giving you the injection.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are given or being treated with Sodium Ascorbate Solution Injection. Sodium Ascorbate Solution
Injection helps most people with
Vitamin C deficiency and related
disorders, but it 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.

Ask your doctor or pharmacist to answer any questions you may have

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

- shortness of breath, troubled breathing, tightness of chest, wheezing
- reddened skin
- · fever
- · general weakness or discomfort
- · skin rash or itching
- nausea, vomiting, diarrhoea, or abdominal pain
- · headache or dizziness

These are rare allergic side effects and may require urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You should not experience any of them.

How to Store Sodium Ascorbate Solution Injection

Unopened bags or vials of Sodium Ascorbate Solution Injection are to be stored at 2 °C to 8 °C (Refrigerate. Do not freeze).

Keep out of reach of children.

This product is for SINGLE USE in one patient on one occasion. only. It is for use in one patient on one occasion only and any left over must be discarded.

Product Description

What it looks like:

Sodium Ascorbate Solution Injection comes in plastic bags or glass vials (bottles).

Sodium Ascorbate Solution
Injection is a clear and colourless or slightly straw coloured solution.
When it is first made it is less straw coloured and as it gets older and toward the end of the expiry date it becomes more straw coloured.

Sodium Ascorbate Solution Injection is packed in the following sizes and concentrations:

- 30 g in 100 mL Vial or Bag
- 15 g in 50 mL Vial or Bag
- 15 g in 100 mL Vial or Bag
- 45 g in 500 mL Bag

Ingredients:

Sodium Ascorbate Solution Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

All bags or vials of Sodium Ascorbate Solution Injection contain the following Ingredients:

Active Ingredient:

Sodium ascorbate

Other Ingredients

Water for injections.

Supplier

Biological Therapies Sodium Ascorbate Solution Injection for Intravenous Infusion is supplied and manufactured in Australia by:

Biological Therapies

A Division of Orthomolecular Medisearch Laboratories Pty Ltd. Suite 5, 20-30 Malcolm Road Braeside VIC 3195 Australia

Tel: +61 3 9587 3948 Fax: +61 3 9587 1720

Website:

www.biologicaltherapies.com.au Email: biol@biol.com.au

Australian Registration Numbers:

Biological Therapies Sodium Ascorbate Solution Injection for Intravenous Infusion

30 g in 100 mL Vial - AUST R 47757

15 g in 50 mL Vial - AUST R 22283

15 g in 100 mL Vial - AUST R 22282

 $30~\mathrm{g}$ in $100~\mathrm{mL}$ Bag - AUST R 47750

15 g in 50 mL Bag - AUST R 22254

15 g in 100 mL Bag - AUST R 22284

45 g in 500 mL Bag – AUST R 22286

Date this document last updated: 27 September 2018

