

Biological Therapies Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution 50 mL Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given this medicine?

This medicine contains the active ingredients Disodium Edetate and Sodium Ascorbate. This medicine may be used to

- remove small amounts of lead from the body if the lead is causing problems in the body
- remove metals, which may be radioactive
- remove excess calcium from the blood if the excess calcium is causing problems in the body, or
- control abnormal heart beat which is caused by an overdose of the drug called digitalis.

For more information, see Section [1. Why am I being given this medicine?](#) in the full CMI.

2. What should I know before I am given this medicine?

Do not use if you have ever had an allergic reaction to this medicine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Disodium Edetate + Sodium Ascorbate Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is this medicine given to me?

This medicine will be infused intravenously (slowly injected into a vein) by your doctor. The amount given depends on many factors including your body weight and medical condition. More instructions can be found in Section [4. How is this medicine given to me?](#) in the full CMI.

5. What should I know while being given this medicine?

Things you must do	<ul style="list-style-type: none">• Remind or tell any doctor, surgeon, anaesthetist, dentist or pharmacist you visit that you are being treated with Disodium Edetate + Sodium Ascorbate Injection.• Tell your doctor if you feel that giving this medicine is not helping your condition.• Keep all of your doctor's appointments so that your progress can be checked.
Things you must not do	<ul style="list-style-type: none">• Do not take any other medicines without first telling your doctor or consulting a pharmacist.• Do not give this medicine to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• This medicine is usually stored in the doctor's surgery or clinic, or at the pharmacy, in a cool dry place, where the temperature stays below 25°C and children cannot reach it. Each vial is for SINGLE USE in one patient on one occasion only.

For more information, see Section [5. What should I know while being given this medicine?](#) in the full CMI.

6. Are there any side effects?

The more common side effects of this medicine are skin irritation, pain or bruising the injection site, stomach cramps, diarrhoea, dizziness or light-headedness, a general feeling of being unwell, cloudy urine or changes in your urination habits, pain or difficulty urinating. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Biological Therapies Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution 50 mL Injection

Active ingredient(s): *Disodium Edetate, Sodium Ascorbate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Biological Therapies Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution in 50 mL Injection for Intravenous Infusion. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Disodium Edetate + Sodium Ascorbate Injection.**

Where to find information in this leaflet:

- [1. Why am I being given this medicine?](#)
- [2. What should I know before I am given this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is this medicine given to me?](#)
- [5. What should I know while being given this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given this medicine?

Disodium Edetate + Sodium Ascorbate Concentrated Injection must be diluted before it is injected.

Disodium Edetate + Sodium Ascorbate Injection contains the active ingredients Disodium Edetate and Sodium Ascorbate.

Disodium Edetate belongs to a group of substances called chelating agents. Chelating agents are used to remove high levels of mineral deposits from the body. They work by tightly binding on to the mineral so that it can be excreted from the body, usually in the urine. Sodium Ascorbate also has mild chelating properties.

This medicine may be used to remove small amounts of lead from the body if the lead is causing problems in the body.

Since Disodium Edetate will bind to a wide range of metals, it will also bind with various toxic and radioactive metals that you may have ingested or inhaled, such as radioactive calcium, strontium, radium cobalt and plutonium. Disodium Edetate will not treat radiation poisoning; it is used only to remove metals, which may be radioactive.

Too much calcium in the blood is called hypercalcaemia. Disodium Edetate + Sodium Ascorbate Injection can also be used to remove excess calcium from the blood if the excess calcium is causing problems in the body. Disodium

Edetate works by binding with the excess calcium in the blood. The calcium and disodium edetate are then removed from the blood by the kidneys and excreted in the urine.

Disodium Edetate + Sodium Ascorbate Injection can also be used to control abnormal heart beat which is caused by an overdose of the drug called digitalis.

Your doctor may have prescribed Disodium Edetate + Sodium Ascorbate Injection for another reason.

Ask your doctor if you have any questions about why Disodium Edetate + Sodium Ascorbate Injection has been prescribed for you.

Disodium Edetate + Sodium Ascorbate Injection is not addictive.

2. What should I know before I am given this medicine?

Warnings

You must not be given this medicine if:

- You have a known allergy to Disodium Edetate or other EDTA drugs.** Symptoms of an allergic reaction may include skin rash; itchiness; shortness of breath; swelling of the face, lips, mouth or throat.
- You have inadequate kidney function.** Disodium Edetate is mostly excreted in the urine and may make kidney disease worse.
- You have active liver disease.** Disodium Edetate + Sodium Ascorbate Injection should not be given if you have hepatitis or cirrhosis of the liver.
- You have a history of tuberculosis.** Disodium Edetate is mostly excreted in the urine and may make kidney disease worse.
- You are using other chelating agents.** You should not be given Disodium Edetate + Sodium Ascorbate Injection if you are having other chelating medicines given by mouth or by injection, unless your doctor recommends it.
- The contents of the bottle have not been diluted before injection.** Disodium Edetate + Sodium Ascorbate Injection **MUST** be diluted before injection.

- The solution for injection is not clear or contains particles
- **The solution has not been prepared on the same day as it is to be given.** Significant changes in acidity can occur in the diluted solution if it is not used on the same day as preparation and this can be harmful to you.

If you are not sure whether you should have Disodium Edetate + Sodium Ascorbate Injection given, talk to your doctor.

Check with 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
- or have had kidney disease, kidney stones or problems passing urine.
- high blood pressure
- a history of heart failure or heart disease
- a history of seizures or epilepsy
- a history of Tuberculosis
- low levels of calcium or potassium in the blood
- haemochromatosis, thalassaemia, polycythemia, leukaemia or sideroblastic anaemia due to enhanced absorption of dietary iron.
- high uric acidity.
- high sodium levels.
- Sickle Cell Anaemia.
- G6PD (Glucose-6-phosphate dehydrogenase) Deficiency.

If you have not told your doctor about any allergies you might have, tell them before you have Disodium Edetate + Sodium Ascorbate Solution Injected.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using Disodium Edetate + Sodium Ascorbate Injection while pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given Disodium Edetate + Sodium Ascorbate Injection.

3. What if I am taking other medicines?

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

Some medicines may interfere with Disodium Edetate + Sodium Ascorbate Injection and affect how it works.

These include:

- Medicines used to treat heart disease such as Digoxin;
- Other Chelation Medicines such as DMPS, DMSA, D-Penicillamine;
- Anticoagulants;
- Vitamin and Mineral Supplements
- Aspirin
- Iron Oral Supplements
- Alcohol
- Amphetamine or other anti-depressants
- 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 Disodium Edetate + Sodium Ascorbate Injection, or affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information about medicines to be careful with, or avoid while you are being treated with this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Disodium Edetate + Sodium Ascorbate Injection.

4. How is this medicine given to me?

This medicine must only be given by a doctor or nurse.

Disodium Edetate + Sodium Ascorbate Solution is a Concentrated Injection and must be diluted with a compatible intravenous solution before use.

Other medicines will be mixed with Disodium Edetate + Sodium Ascorbate Injection before it is given to you.

It will then be infused intravenously (slowly injected into a vein) by your doctor. Your doctor will decide the best way to do this.

Disodium Edetate + Sodium Ascorbate Injection must be used on the same day it is mixed or diluted.

It is recommended you stop taking any mineral supplements 24 hours before Disodium Edetate + Sodium Ascorbate Injection is given. Your doctor will advise you about this.

How much is given

Your doctor will tell you how much Disodium Edetate + Sodium Ascorbate Injection will need to be given and for how long it is to be given. This is determined by many factors including your body weight and your medical condition.

The maximum dose of Disodium Edetate in any 24-hour period is 3 grams.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How long is the treatment time with this medicine

Each person will respond differently to Disodium Edetate + Sodium Ascorbate Injection.

Treatment times will differ depending on the reason for prescribing Disodium Edetate + Sodium Ascorbate Injection.

Your treatment using Disodium Edetate + Sodium Ascorbate Injection will be individually tailored to your needs by your doctor. It is usual that several treatments may be necessary. Each treatment may take 3-4 hours, however your doctor will advise you as to the length and frequency of treatment.

If you miss an appointment or need to change an appointment

If you miss an appointment, talk to your doctor and arrange 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 of this medicine is given

Your doctor should be the only person to inject Disodium Edetate + Sodium Ascorbate Injection, so an overdose is unlikely to occur.

If you think that you or anyone else may have been given too much Disodium Edetate + Sodium Ascorbate Injection you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given this medicine?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Disodium Edetate + Sodium Ascorbate Injection.
- Tell all doctors, dentists and pharmacists who treat you that you are being given this medicine.
- Tell your doctor if you become pregnant while being treated with Disodium Edetate + Sodium Ascorbate Injection.
- Tell your doctor if you feel that giving Disodium Edetate + Sodium Ascorbate Injection is not helping your condition.
- Disodium Edetate + Sodium Ascorbate treatment must be monitored very closely by your doctor. You may need to have regular blood tests and urine tests, and have your blood pressure checked regularly.
- Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

- Do not attempt to inject this medicine yourself.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.
- Do not use this medicine if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful driving or operating machinery until you know how Disodium Edetate + Sodium Ascorbate Injection affects you.

This medicine may cause dizziness, light-headedness or weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution in 50 mL Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store Disodium Edetate + Sodium Ascorbate Injection keep it in the original pack until it is time for it to be given.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

When to discard your medicine

Each vial is for SINGLE USE in one patient on one occasion only. It will be used once only and then it will be discarded. It must never be stored after it is opened or used for more than one person.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any vials that are left over.

Do not use this medicine after the expiry date. If you have this medicine after the expiry date, it may not work and it may be harmful to you.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or treated with Disodium Edetate + Sodium Ascorbate Injection.

This medicine helps most people, 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 attention if you get some of the side effects.

Do not be alarmed by the following lists. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Skin irritation and/or pain around the area of injection• Bruising around the area of injection• Stomach cramps• Diarrhoea• Dizziness or light-headedness• A general feeling of being unwell• cloudy urine or changes in your urination habits• Pain or difficulty urinating	Speak to your doctor, nurse or pharmacist if you notice any of these less serious side effects and they worry you.

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Headache• Tingling feeling or pins and needles, numbness or prickling feelings• Temporary numbness of the mouth, or temporary numbness anywhere else• Flu like symptoms such as chills or fever Burning, crawling or itching feeling• Sores in the mouth and on lips and dry scaly skin	Speak to your doctor or nurse as soon as possible, if you have any of these serious side effects.

The above list includes serious side effects that may require medical attention or hospitalization.

Very serious side effects	What to do
<ul style="list-style-type: none">• unexplained back pain• extreme numbness or tingling, difficulty moving fingers or toes• Muscle spasms or tremors• Excessive thirst• Pain, burning or swelling at the site of injection• Unusual tiredness or weakness• Skin rashes or sores• Flu like symptoms such as chills or fever• Severe pain or inflammation of the feet, knees, hands, or elbows• shortness of breath, troubled breathing, tightness of chest, wheezing• nausea or vomiting	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> • Symptoms caused by low levels of calcium in the blood <ul style="list-style-type: none"> • Difficulty breathing • Irregular heartbeat • Mood or mental changes • Muscle spasms in hands, arms, feet, legs or face • Numbness or tingling around the mouth, fingertips or feet • Fits or seizures <p>Symptoms of an overdose:</p> <ul style="list-style-type: none"> • Abdominal cramps • Shortness of breath or difficulty breathing • Irregular heartbeat • Confusion, mood or mental changes • Muscle cramps in hands, arms, feet, legs or face • Numbness and tingling around the mouth, fingertips or feet • Shaking or tremors • Convulsions, fits or seizures. 	
---	--

The above list are rare side effects and you may need urgent medical attention.

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution in 50 mL Injection contains

Active ingredient (main ingredient)	Disodium Edetate Sodium Ascorbate
--	--------------------------------------

Other ingredients (inactive ingredients)	Water for injections
---	----------------------

Do not take this medicine if you are allergic to any of these ingredients.

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

What Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution in 50 mL Injection looks like

Biological Therapies Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution 50 mL Injection is a clear and colourless solution in a clear glass vial, sealed with a rubber stopper and an aluminium cap.

1 x 50 mL vial per carton.

Australian Registration Number: AUST R 22289.

Who distributes Disodium Edetate 3 g + Sodium Ascorbate 5 g Solution in 50 mL Injection

Biological Therapies

A Division of Orthomolecular Medisearch Laboratories Pty Ltd

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

This leaflet was prepared in October 2025.



Biological Therapies