

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

Concentrated Injection for Intravenous Infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Disodium Edetate 3g + Sodium Ascorbate 5g Solution in 50mL Concentrated 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 Disodium Edetate + Sodium Ascorbate 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 Disodium Edetate + Sodium Ascorbate Injection is used for

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

Disodium Edetate + Sodium Ascorbate Concentrated 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.

Disodium Edetate + Sodium Ascorbate Injection is only available from a medical practitioner.

Before you are given Disodium Edetate + Sodium Ascorbate Injection

When you must not be given it:

Do not have Disodium Edetate + Sodium Ascorbate Injection given 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 Concentrated 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.
- **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 Disodium Edetate + Sodium Ascorbate 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 Disodium Edetate + Sodium Ascorbate 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 or have had kidney disease, kidney stones or problems passing urine.**
- **Tell your doctor if you have high blood pressure**
- **Tell your doctor if you have a history of heart failure or heart disease**
- **Tell your doctor if you have a history of seizures or epilepsy**
- **Tell your doctor if you have a history of Tuberculosis**
- **Tell your doctor if you have low levels of calcium or potassium in the blood**
- **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 intending to become pregnant**
- **Tell your doctor if you are breastfeeding or are intending 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 allergies you might have, tell them before you have Disodium Edetate + Sodium Ascorbate Solution Injected.

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 Disodium Edetate + Sodium Ascorbate Injection may interfere with each other. 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 may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

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.

Your doctor or pharmacist has more information about medicines to be careful with, use correctly or to avoid while you are being treated with Disodium Edetate + Sodium Ascorbate Injection.

How Disodium Edetate + Sodium Ascorbate Injection is given

Disodium Edetate + Sodium Ascorbate Injection 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.

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 to use it:

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 or treatment.

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 Disodium Edetate + Sodium Ascorbate Injection, so an overdose is not likely to occur.

But if you think that you or anyone else may have been given too much Disodium Edetate + Sodium Ascorbate 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.

Immediately contact your doctor or nurse if you notice the following symptoms of an overdose:

- 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.

While you are being given Disodium Edetate + Sodium Ascorbate Injection

Things you must do:

- **Tell all doctors, dentists and pharmacists who are treating you that you are being treated with Disodium Edetate + Sodium Ascorbate Injection.**
- **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 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.

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

Things you must not do:

- **Do not inject Disodium Edetate + Sodium Ascorbate Solution 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:

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

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.

Disodium Edetate + Sodium Ascorbate Injection 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 treatment if you get some of the side effects.

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

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

- 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

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

Tell your doctor or nurse as soon as possible if you notice any of the following

- 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

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

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- 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
- Symptoms caused by low levels of calcium in the blood
 - 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

These are rare 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 may not experience any of them.

How to Store Disodium Edetate + Sodium Ascorbate Concentrated Injection

Store below 25°C.

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

Ingredients:

Active Ingredients:

Disodium Edetate 3g

Sodium Ascorbate 5g

Other Ingredients

Water for Injections.

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

What it looks like:

Disodium Edetate + Sodium Ascorbate in 50mL Concentrated Injection is a clear and colourless solution in a clear glass vial, sealed with a rubber stopper and an aluminium cap.

Supplier

Disodium Edetate 3g + Sodium Ascorbate 5g in 50mL Concentrated Injection 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

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