

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ASCORBIC ACID 500 mg/5 ml FRESENIUS solution for injection

Ascorbic acid

Sugar free

Read all of this leaflet carefully before you are given ASCORBIC ACID 500 mg/5 ml FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ASCORBIC ACID FRESENIUS is and what it is used for
2. What you need to know before you are given ASCORBIC ACID FRESENIUS
3. How ASCORBIC ACID FRESENIUS is given
4. Possible side effects
5. How to store ASCORBIC ACID FRESENIUS
6. Contents of the pack and other information

1. What ASCORBIC ACID FRESENIUS is and what it is used for

ASCORBIC ACID FRESENIUS contains ascorbic acid, also known as vitamin C. Your body needs ascorbic acid for growth and health. A normal diet will provide sufficient ascorbic acid for your body.

A lack of ascorbic acid (vitamin C) causes a disease called scurvy, the symptoms of that include gum problems, bleeding under the skin, the opening of previously healed wounds and weakness.

Although ascorbic acid is available in oral dosage forms, ascorbic acid is administered by injection in severe deficiency states and where persistent vomiting, diarrhoea or other conditions preventing ascorbic acid being taken by mouth.

2. What you need to know before you are given ASCORBIC ACID FRESENIUS

ASCORBIC ACID FRESENIUS should not be administered to you:

- If you are hypersensitive (allergic) to ascorbic acid, or any of the other ingredients of ASCORBIC ACID FRESENIUS (see section 6)
- If you have a condition called hyperoxaluria, where you have high levels of oxalic acid or oxalates in your urine
- if you have kidney stones.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have kidney disease
- if you have an enzyme deficiency called glucose-6-phosphate dehydrogenase (G6PD) deficiency (a lack of an enzyme in the red blood cells)
- if you are to undergo any blood or urine tests as ascorbic acid can interfere with some blood and urine tests
- if you smoke (smoking can make ascorbic acid less effective).

Other medicines and ASCORBIC ACID FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor, pharmacist or health care provider if you are taking any of the following medicines

- desferrioxamine a medicine that combines with iron in the body normally used in the treatment of iron poisoning
- oral contraceptives which contain oestrogen (e.g., “the pill”)
- tranquillizers (fluphenazine)
- iron products for the treatment of anaemia
- aspirin (a medicine used to reduce pain, fever or inflammation)
- appetite suppressants
- medicines used to treat epilepsy (e.g., phenytoin)
- antibiotics (e.g., tetracycline)
- medicines used to prevent blood clots (e.g., warfarin)
- aluminium containing products such as antacids medicines used to relieve heartburn and/or acid indigestion.

ASCORBIC ACID FRESENIUS with food, drink and alcohol

Do not drink alcohol whilst you are having ASCORBIC ACID FRESENIUS, because alcohol reduces the amount of ascorbic acid in your blood.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving ASCORBIC ACID FRESENIUS.

Driving and using machines

It is not always possible to predict to what extent ASCORBIC ACID FRESENIUS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASCORBIC ACID FRESENIUS affects them.

ASCORBIC ACID FRESENIUS contains sodium

ASCORBIC ACID FRESENIUS contains 66 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 3 % of the recommended maximum daily dietary intake of sodium for an adult

3. How ASCORBIC ACID FRESENIUS is given

You will not be expected to give yourself ASCORBIC ACID FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will decide what the dose is and for how long you will receive ASCORBIC ACID FRESENIUS. This will vary from patient to patient. It will depend on your condition and other factors, such as your physical condition, weight, age as well as other medicines that you are taking at the time or after. For most conditions, the ASCORBIC ACID FRESENIUS injection is usually given in divided doses throughout the day.

Normally it is injected directly into the muscle (intramuscular), or into the vein (intravenous) or under the skin (subcutaneous).

If you receive more ASCORBIC ACID FRESENIUS than you should

Since a health care provider will administer ASCORBIC ACID FRESENIUS, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

ASCORBIC ACID FRESENIUS can have side effects.

Not all side effects reported for ASCORBIC ACID FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ASCORBIC ACID FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving ASCORBIC ACID FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ASCORBIC ACID FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Breakdown of red blood cells (symptoms include weakness, confusion, dark urine, yellowing of the skin and eyes, dark urine).
- Blood disorders (symptoms include tiredness, headaches, dizziness, paleness of the skin, frequent infections such as fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal, nosebleeds).
- Kidney problems, formation of kidney stones, passing more urine than normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown

- Gastrointestinal disturbances (symptoms of stomach pain, heartburn diarrhoea,

constipation, nausea (feeling sick), and vomiting (being sick)).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of ASCORBIC ACID FRESENIUS.

Report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicine’s regulatory authority in the country where the product is marketed.

5. How to store ASCORBIC ACID FRESENIUS

Store all medicines out of reach of children.

ASCORBIC ACID FRESENIUS will be stored in the pharmacy or in the hospital wards. The injection is kept in a cool dry place at a temperature at or below 25 °C.

It is protected from light.

6. Contents of the pack and other information

What ASCORBIC ACID FRESENIUS contains:

- The active substance is ascorbic acid. Each 5 ml contains 500 mg ascorbic acid.
- The other ingredients are sodium bicarbonate (for pH-adjustment) and water for injection.

What ASCORBIC ACID FRESENIUS looks like and contents of the pack

5 ml colourless or pale-yellow solution in amber OPC glass ampoules.

Pack size of 10 ampoules in an outer cardboard carton.

Holder of Certificate of Registration

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: +27 (0)41 403 1600

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