

**PACKAGE LEAFLET**

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**Package leaflet: Information for the user****Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

ascorbic acid

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion is and what it is used for
2. What you need to know before you use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion
3. How to use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion
4. Possible side effects
5. How to store Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion
6. Contents of the pack and other information

**1. What Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion is and what it is used for**

Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion is intended for the treatment of clinical vitamin C deficiency states not amenable to dietary supply or intake of vitamin C preparations.

Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion contains the essential active substance ascorbic acid (vitamin C) that cannot be produced internally by the human body.

Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion is indicated in adults.

## **2. What you need to know before you use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

### **Do not use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion:**

- if you are allergic to vitamin C or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from oxalate urolithiasis (a type of kidney or bladder stones) or hyperoxaluria (a condition, where you have too much oxalate in your urine)
- if you suffer from an iron storage disorder/iron overload (e. g. thalassemia, hemochromatosis, sideroblastic anemia, erythrocyte concentrate transfusions)
- if you have a severe renal insufficiency (impaired kidney function)
- if you have a glucose-6-phosphate dehydrogenase deficiency/defect (inherited disorder of red blood cell metabolism)
- if you are under 12 years of age

### **Warnings and precautions**

Talk to your doctor before using Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion.

Take special care with Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion

- if you have been advised to follow a low salt (sodium) diet. 1 vial of 50 ml of the product contains 972 mg sodium.
- if you had difficulties in breathing in the past, such as a bronchospasm or a lung disease. If this applies to you, your doctor will choose a lower starting dose.
- if you need to perform certain laboratory tests (such as tests for glucose, uric acid, creatinine, inorganic phosphate): Ascorbic acid might influence the test results and thus lead to false results. In this case, your doctor will inform you if for 1 day before such a test is conducted, no vitamin C should be given to you.

Note for diabetic patients:

Parenterally administered ascorbic acid interferes with the blood glucose determination assay.

During your treatment with Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion, it is important that you pay attention to your daily intake of water (approximately 1.5 – 2 l per day).

In order to reduce the risk for formation of kidney or urinary stones, it is recommended to avoid any additional oxalate-rich food (e.g. rhubarb, spinach, beetroot, etc.) during your treatment with Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion.

If you have suffered from recurring kidney stones in the past, a maximum daily dose of 100-200 mg vitamin C should not be exceeded, as there is an increased risk for the formation of calcium oxalate stones.

### **Children and adolescents**

Children under 12 years should not receive more than 5-7 mg ascorbic acid/kg body weight per day. High doses of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion are contraindicated in children under 12 years. There are no data available on the use of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion in adolescents.

**Other medicines and Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

The following medicinal drugs reduce the concentration of vitamin C in your body and thus might reduce the effectiveness of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion

- Acetylsalicylic acid (anti-inflammatory drug) such as aspirin
- Nicotine from cigarettes
- Alcohol
- Appetite suppressants (e.g. fenfluramine)
- Iron (taken as food supplement)
- Medicines used to treat epilepsy (e.g. phenytoin)
- Oral contraceptives which contains oestrogen (e.g. “the pill”)
- antibiotics (e.g. tetracycline)
  
- Fluphenazine (for mental disorders): Blood concentrations might decrease due to Vitamin C therapy

The simultaneous intake of vitamin C with desferrioxamine mesilate t/Desferal (used in case of iron overload) can cause a disturbance of the heart function.

Large doses of vitamin C may lower the effectiveness of oral anticoagulants.

Note for patients with kidney failure:

Aluminium antacids in combination with vitamin C may lead to higher blood aluminium levels.

Due to lack of comprehensive clinical data, higher dosages of vitamin C should take place time-displaced to chemotherapy or radiotherapy. Is vitamin C infused before the chemo-/radiotherapy, a temporal distance of 24 hours is recommended. If vitamin C is administered after chemo-/radiotherapy, an interval of at least 24 hours should be maintained. For chemotherapeutics where it takes > 6 hours until the concentration of the active substance in the blood plasma has been reduced by half (= half-life), an interval of 3-4 half-lives should be maintained.

**Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion with food and drink**

No interactions are expected.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ascorbic acid is excreted in the unborn child's circulation and in breastmilk. Daily doses of 100 to 500 mg ascorbic acid should not be exceeded in pregnant women and nursing mothers.

Due to its high vitamin C content, do not use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion if you are pregnant or if you are breast-feeding.

There are no studies on the influence on fertility.

**Driving and using machines**

If side effects like dizziness, nausea or troubled vision occur (see section 4. "Possible side effects"), your ability to drive or use machinery may be affected.

### **Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion contains sodium**

Each injection vial of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion contains 42.3 mmol (972 mg) sodium.

To be taken into consideration by patients on a controlled sodium diet.

### **3. How to use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

#### **Adults:**

The usual dose is 0.5 to 1.0 g ascorbic acid (corresponding to 3.3 – 6.7 ml concentrate). Severe trauma or surgery can require higher daily dosages of at least 3 g ascorbic acid to restore normal plasma levels. Depending on the disease situation, up to 7.5 g ascorbic acid (50 ml concentrate) per day may be used for infusion.

#### **Paediatric population:**

Children younger than 12 years of age must not receive more than 5-7 mg ascorbic acid/kg body weight per day. High doses of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion are contraindicated in children under 12 years. There are no data available on the use of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion in adolescents.

#### **Method of administration**

For slow injection or infusion into a vein. Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion has to be diluted before use.

For the dilution instruction please see the section "The following information is intended for healthcare professionals only" at the end of the document.

Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion will be given by your doctor.

The duration of use depends on the course of the illness and the results of laboratory tests.

### **If you use more Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion than you should**

For the risk of kidney stone formation see under section 2. "Warnings and precautions".

### **If you forget to use Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

Consult your doctor to decide on the further dosage.

### **If you stop using Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion**

By stopping the use of this medicine, you jeopardize the success of the treatment! If you experience unpleasant side effects, discuss the further treatment with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effect, contact you doctor immediately, usually he will promptly discontinue the injection/infusion.

#### Very rare: may affect up to 1 in 10,000 people

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- Respiratory hypersensitivity reactions, e.g. shortness of breath.
- Skin hypersensitivity reactions, e.g. rash, hives, itching.
- Transient circulation problems (e.g. dizziness, nausea, headache, troubled vision)
- Reactions such as chills and elevated temperature were observed in patients with acute infections
- Gastrointestinal disorders e.g. nausea, vomiting, diarrhoea
- Renal oxalate calculi
- Increase in urination

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion

Do not store above 25°C

Keep the vial in the outer carton in order to protect it from light.

The preservative-free concentrate for solution for injection/infusion is for **single** use only. It has to be used immediately after opening. Any unused solution must be discarded.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

#### 6. Contents of the pack and other information

##### What Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion contains

- The active substance is: ascorbic acid
- 1 vial with 50 ml solution for injection/ infusion contains 7.5 g ascorbic acid

- The other ingredients are: Sodium bicarbonate and water for injections
- 50 ml of the product contain 972 mg sodium

### **What Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion looks like and contents of the pack**

Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion is a clear, light yellow concentrate for solution for intravenous injection/infusion.

Each pack contains 1 vial with 50 ml of concentrate for solution for injection/infusion.

### **Marketing Authorisation Holder**

Pascoe pharmazeutische Präparate GmbH  
Schiffenberger Weg 55  
35394 Giessen  
Germany

### **Manufacturer**

Pascoe pharmazeutische Präparate GmbH  
Europastr. 2  
35394 Giessen  
Germany

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria: Vitamin C Pascoe, 150mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung

Denmark: Ascorbinsyre Pascoe

Finland: Ascorbic Acid Pascoe 150 mg/ml Konsentraatti injektioneste- / infuusioliuosta varten

Luxembourg: Pascorbin 150mg/ml Konzentrat zur Herstellung einer Injektions-/Infusionslösung

Malta: Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection/infusion

Norway: Vitamin C Pascoe

Portugal: Pascorbin 150 mg/ml Concentrado para solução injectável / para perfusão

Sweden : Ascorbic Acid Pascoe 150 mg/ml Konzentrat för injektionsvätska, lösning

United Kingdom: Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion

**This leaflet was last revised in August 2020.**

### **The following information is intended for healthcare professionals only:**

#### Instructions for use/handling

Prior to use, Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion must be diluted with NaCL solution. A dilution ratio of one part of Ascorbic Acid Pascoe 150 mg/ml Concentrate for solution for injection / infusion plus 2 parts of isotonic saline solution is recommended.