PACKAGE LEAFLET: INFORMATION FOR THE USER

Dr. Scheffler Vitamin C, 1000 mg, effervescent tablets

Ascorbic Acid

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

- 1. What Dr. Scheffler Vitamin C is and what it is used for
- 2. What you need to know before you take Dr. Scheffler Vitamin C
- 3. How to take Dr. Scheffler Vitamin C
- 4. Possible side effects
- 5. How to store Dr. Scheffler Vitamin C
- 6. Contents of the pack and other information

1. What Dr. Scheffler Vitamin C is and what it is used for

Dr. Scheffler Vitamin C effervescent tablets are used for the treatment of vitamin C deficiency diseases (e. g. scurvy).

2. What you need to know before you take Dr. Scheffler Vitamin C

Do not take Dr. Scheffler Vitamin C:

- if you are allergic to ascorbic acid (vitamin C) or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from kidney stones (oxalate) unless advised by your doctor.
- if you suffer from certain illnesses where too much iron is absorbed by the body (thalassaemia, haemochromatosis, sideroblastic anaemia).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Dr. Scheffler Vitamin C.

Take special care with Dr. Scheffler Vitamin C

- if you suffer from hereditary disorders of red blood cells (e. g. Glucose-6-Phosphate dehydrogenase deficiency), do not exceed the recommended dose (1000mg per day).
- if you take an increased dose of vitamin C over prolonged periods, a lack of vitamin C is possible when stopping the treatment. An increased intake may result in an increase in renal clearance of vitamin C.
- if you are at risk of recurring formation of kidney stones, you should not exceed a daily vitamin C-intake of 100 to 200 mg (see also the section "Do not take Dr. Scheffler Vitamin C"). In case of susceptibility to kidney stones, there is the risk of the formation of kidney stones (calcium oxalate calculi) due to the intake of high doses of vitamin C.
- if you suffer from severe kidney disease (dialysis patients), do not take a daily vitamin C dose exceeding 50 to 100 mg of vitamin C, because otherwise there is the risk of developing high concentrations of oxalate in the blood (hyperoxalataemia) with the formation of crystals of salt (oxalate) in the kidneys Please consult your doctor about this matter.
- avoid high vitamin C doses if you suffer from renal failure and if you take medicinal products with negative effect on the renal function (see section "Other medicines and Dr. Scheffler Vitamin C").
- The administration of gram doses can elevate the ascorbic acid concentration in the urine to such a degree that the measurement of various clinical-chemical parameters (glucose, uric acid, creatinine, inorganic phosphate) is impaired. Likewise, gram doses can lead to false-negative results in the attempted detection of occult blood in the stools. Generally, chemical detection methods which are based on colour reactions can be affected.

Children and adolescents

Dr. Scheffler Vitamin C is not intended for use in children and adolescents (below 18 years). Medicinal products containing lower doses of Vitamin C are available for them.

Other medicines and Dr. Scheffler Vitamin C

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Although the following interactions between vitamin C and other substances are described it is not known if they are of importance when using Dr. Scheffler Vitamin C as directed:

- Vitamin C in a dosage of 1 g daily increases the absorption of oral contraceptives (oestrogens).
- Corticosteroids and calcitonin increase the rate at which vitamin C is processed by the body.
- Salicylic acid derivatives such as acetylsalicylic acid inhibit the uptake of vitamin C from the digestive system.
- Antibiotics such as tetracyclines inhibit the use of vitamin C in the body cells.
- Acetylsalicylic acid, barbiturates such as phenobarbital and antibiotics such as tetracyclines increase vitamin C excretion in the urine.
- Vitamin C can decrease the therapeutic effect of blood thinning medication, such as warfarin and the antipsychotic drugs phenothiazines such as fluphenazine.

- Taking high doses of vitamin C over a long period can influence the interaction between disulfiram and alcohol.
- High doses of vitamin C taken together with iron supplements may cause an iron overload due to an increased absorption of iron into the body.
- High doses of vitamin C taken together with aluminium (e.g. antacids such as aluminium hydroxide, magaldrate) may cause increased absorption of aluminium into the body.
- Vitamin C can decrease the amount of cyclosporine A, a medicine used to suppress the immune system, in the blood.

Dr. Scheffler Vitamin C with food, drink and alcohol

Alcohol reduces ascorbic acid levels.

Pregnancy, breast-feeding and fertility

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 any medicine.

Do not take Dr. Scheffler Vitamin C before asking your doctor for advice if you are pregnant or breast-feeding.

There is limited amount of data from the use of high dose vitamin C in pregnant women. It is not clear if vitamin C supplementation in amounts exceeding Dietary Reference Intake recommendations is safe or beneficial.

Vitamin C is secreted into breast milk and crosses the placenta. There is insufficient information on the effects of high dose vitamin C in newborns/ infants.

Driving and using machines

Not applicable.

Dr. Scheffler Vitamin C contains sodium, colourings (orange yellow S $(E\ 110)$, azorubine $(E\ 122)$ and sorbitol.

This medicinal product contains 321 mg sodium per dose, and people who have been advised to restrict the use of salt (e. g. patients with high blood pressure) should take this drug with caution.

The colourings contained in Dr. Scheffler Vitamin C - orange yellow S (E 110) and azorubine (E 122) - can cause allergic reactions, including asthma. Such allergic reactions can occur in particular in persons who are allergic to acetylsalicylic acid.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dr. Scheffler Vitamin C

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is:

Adults take one effervescent tablet (= 1000 mg of ascorbic acid (vitamin C) daily until the symptoms improve.

The maximum therapeutic dose of 1000mg (1 tablet/day) should not be exceeded.

Use in children and adolescents

Dr. Scheffler Vitamin C is not intended for use in children and adolescents (below 18 years). Medicinal products containing lower doses of vitamin C are available for them.

Patients with renal disease

Dr. Scheffler Vitamin C is not intended for use in patients with renal disease. Medicinal products containing lower doses of vitamin C are available for them (see section "Warnings and precautions").

How and when should Dr. Scheffler Vitamin C be taken?

Completely dissolve effervescent tablet in a glass of water. If any residue remains in the glass after drinking the liquid, add more water to the glass and drink the liquid.

For how long should Dr. Scheffler Vitamin C be taken?

It is generally recommended to continue therapy until your symptoms improve. Consult your pharmacist or doctor if in doubt.

If you take more Dr. Scheffler Vitamin C than you should

See "Warnings and precautions" regarding the risk of breakdown of red blood cells (haemolyses) and kidney stones.

Should you experience any pain in the region of the kidneys or have difficulty passing water following a high dose of Dr. Scheffler Vitamin C, you should consult your doctor immediately.

Temporary diarrhoea occasionally occurs after single doses of 3 g, and almost always after more than 10 g of Vitamin C, accompanied by respective abdominal symptoms. The intake of Dr. Scheffler Vitamin C should then be stopped. No other measures are necessary as a rule.

If you forget to take Dr. Scheffler Vitamin C

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dr. Scheffler Vitamin C

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

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, stop taking Dr. Scheffler Vitamin C and tell your doctor immediately or go to the casualty department of the nearest hospital. You may need urgent medical attention or hospitalisation.

Frequency not known (cannot be estimated from the available data)

Hypersensitivity reactions such as

- breathing difficulties
- allergic skin reactions

Orange Yellow (E110) and azorubine (E122) may cause allergic reactions.

Reporting of side effects

If you get any of the side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2

Tel: +353 1 6764971 Fax: +353 1 6762517 Website: <u>www.hpra.ie</u> E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dr. Scheffler Vitamin C

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

The expiry date which is stated on the base of the tube and also on the outer carton.

The expiry date refers to the last day of that month.

Use within 3 months of opening the pack.

Do not store above 25 °C. Keep the container tightly closed to protect from moisture. Store in the original packaging in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dr. Scheffler Vitamin C contains

- The active substance is 1000 mg ascorbic acid (Vitamin C).
- The other ingredients are Anhydrous citric acid, sodium hydrogen carbonate, sorbitol orange flavouring with orange oil and maltodextrin, maize starch, sodium cyclamate, saccharin sodium, povidone K25 colourings: orange yellow S (E 110), azorubine (E 122), indigocarmine (E 132).

What Dr. Scheffler Vitamin C looks like and contents of the pack

Dr. Scheffler Vitamin C are light pink coloured effervescent tablets with dark violet spots, odour of red orange.

10, 20 or 60 effervescent tablets are available in tubes (polypropylene) closed with stoppers (polyethylene) equipped with desiccant (silica gel).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Dr. B. Scheffler Nachf. GmbH & Co. KG Senefelderstrasse 44 D-51469 Bergisch Gladbach Germany

This leaflet was last revised in {07/2014}

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

Germany	Additiva Vitamin C
Belgium	Dr. Scheffler Vitamin C 1000 mg
Ireland	Dr. Scheffler Vitamin C
Luxemburg	Dr. Scheffler Vitamin C 1000 mg
Portugal	Ácido Ascórbico Dr. Scheffler 1000 mg

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Other information:

Fresh fruit and vegetables contain a sufficiently high amount of vitamin C. However, when stored for longer periods the vitamin C can be lost to varying degrees, particularly in potatoes and vegetables. Generally the consumption of this vitamin in central Europe is more than adequate. Older people may be inadequately supplied due to changes in dietary habits. Babies fed with cow milk need to be supplemented with vitamin C.

Besides a poor or deficient diet, extreme physical illness can lead to vitamin C deficiency. A very severe form of vitamin C deficiency is scurvy, which is accompanied by weakness and bleeding throughout the body and is treated medicinally with vitamin C.

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