

Package Leaflet: Information for the User

Redoxon Double Action 1000 mg/10 mg Effervescent Tablets Vitamin C & Zinc

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

This medicine is available without prescription. However, you still need to take Redoxon Double Action carefully to get the best results from them. 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 or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4). You must contact a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Redoxon Double Action is and what is it used for
2. What you need to know before you take Redoxon Double Action
3. How to take Redoxon Double Action
4. Possible side effects
5. How to store Redoxon Double Action
6. Contents of the pack and other information

1. WHAT REDOXON DOUBLE ACTION IS AND WHAT IS IT USED FOR

Redoxon Double Action Effervescent Tablets are a vitamin and mineral supplement containing vitamin C and zinc. Redoxon Double Action Effervescent Tablets are for the treatment of vitamin C and zinc deficiency.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE REDOXON DOUBLE ACTION

DO NOT take Redoxon Double Action:

- if you are allergic to vitamin C or zinc or any of the other ingredients.
- if you suffer or suffered from kidney stones, or have high oxalic levels in the urine.
- if you have severe problems with your kidneys or are on dialysis.
- if you suffer from iron overload (hemochromatosis).

Warnings and Precautions:

Talk to your doctor or pharmacist before taking Redoxon Double Action

- if you have phenylketonuria (PKU). Redoxon Double Action contains a source of phenylalanine. This may be harmful to people with phenylketonuria.
- If you have been told that you have a rare genetic disease causing a deficiency of glucose-6-phosphate dehydrogenase.
- if you are prone to kidney stones, use caution with high dose Vitamin C formulations.

Please consult your doctor or pharmacist before taking Redoxon Double Action if you have any kidney problems. Vitamin C should not be taken in higher doses, or for longer than recommended, as overdose may lead to kidney problems.

Diabetics: Vitamin C can interfere with some test kits used to determine blood sugar content. It has no effect on blood sugar levels. Ask your doctor or pharmacist if your test result can be affected by taking vitamin supplements.

If your doctor recommends that you have any hospital tests, mention to him that you are taking Redoxon Double Action. This is because Vitamin C may interfere with some tests.

Other medicines and Redoxon Double Action:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription or any vitamin supplements.

- If you are taking Desferrioxamine (used to treat iron poisoning), Cyclosporine (an immunosuppressant) or Warfarin (blood thinner) speak to your doctor before taking Redoxon Double Action.
- Please separate the intake of Redoxon Double Action from other medication by 4 hours.

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 for advice before taking this medicine.

Redoxon Double Action contains aspartame, sorbitol and sodium:

Redoxon Double Action contains 15 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicinal product contains 194 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 9.7% of the recommended maximum daily dietary intake of sodium for an adult. This should be taken into consideration by patients on a controlled sodium (salt) diet.

3. HOW TO TAKE REDOXON DOUBLE ACTION

Adults and children over the age of 12 years: 1 effervescent tablet daily, dissolved in a glass of water (200 ml).

Always take Redoxon Double Action exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you take more Redoxon Double Action than you should:

If you overdose on this medicine, you should talk to your doctor.

If you forget to take Redoxon Double Action:

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Redoxon Double Action can cause side effects, although not everybody gets them. If you experience any of the following signs of an allergic reaction, stop taking Redoxon Double Action and go to your nearest Accident & Emergency Department or doctor immediately: difficulty in breathing or swallowing, swelling of the face, lips, throat or tongue, skin rashes, large or itchy wheals on the skin, attacks of sneezing, runny nose and itching eyes or water retention.

Other side effects: diarrhoea, nausea, vomiting, gastrointestinal and stomach pain.

Reporting of side effects

If you get any 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, Website: www.hpra.ie

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

5. HOW TO STORE REDOXON DOUBLE ACTION

Store below 25°C. Keep the tube tightly closed to protect from moisture. A desiccant is enclosed in the cap.

Keep out of the sight and reach of children.

Do not allow children to play with the empty packaging as they could swallow the desiccant included in the packaging.

Do not use Redoxon Double Action after the expiry date which is stated on the base of the tube. The expiry date refers to the last day of that month.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Redoxon Double Action contains:

1 effervescent tablet contains the active ingredients Ascorbic acid (vitamin C) 1000 mg and Zinc (as zinc citrate trihydrate) 10 mg. 1000 mg of ascorbic acid (vitamin C) equals 1250 % of the RDA and 10 mg of zinc (as zinc citrate trihydrate), equals 100 % RDA. RDA = recommended daily allowance.

The other ingredients are sodium hydrogen carbonate, anhydrous sodium carbonate, anhydrous citric acid, sorbitol (E420), aspartame (E951), acesulfame potassium, sodium chloride, orange flavour (contains acetaldehyde, ascorbic acid, ethyl butyrate, decanal, dodecanal, hexanal, orange oil, linalol, tetradecanal, nonalal, octanal, acacia and maltodextrin), tangerine flavour (contains ascorbic acid, tangerine oil, acacia and maltodextrin) and betacarotene 1% (contains beta carotene crystalline, alpha tocopherol, sodium ascorbate crystalline, medium chain triglycerides, acacia, sucrose, maltodextrin and silicon dioxide).

What Redoxon Double Action looks like and contents of the pack:

Redoxon Double Action effervescent tablets are light orange, round tablets, flat on both sides. The tablets are available in pack sizes of 10, 15, 20 and 30. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Bayer Ltd, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland

Manufacturer: Delpharm Gaillard, 33 Rue de L'Industrie, 74240 Gaillard, France.

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

Ireland: Redoxon Double Action 1000mg/10mg

Effervescent Tablets

This leaflet was last approved in September 2022