Package leaflet: Information for the user

Solvazinc 45mg Effervescent Tablets (Zinc)

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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.

In this leaflet:

- 1. What Solvazinc is and what it is used for
- 2. What you need to know before you take Solvazinc
- 3. How to take Solvazinc
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1. What Solvazinc is and what it is used for

Solvazinc is a mineral supplement used for the treatment of zinc deficiency. Solvazinc 45mg Effervescent Tablets contain zinc (as zinc sulfate monohydrate). Zinc sulfate monohydrate is a source of zinc, which is an essential trace element and involved in a number of body enzyme functions. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Solvazinc

Do not take Solvazinc

- if you are allergic (hypersensitive) to zinc sulfate monohydrate or any of the other ingredients of this medicine (listed in section 6).
- if you have copper deficiency

Talk to your doctor if this applies to you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Solvazinc if you suffer from kidney disease.

If this applies to you it is important that you tell your doctor or pharmacist before taking Solvazinc and they will decide what to do. It may still be safe for you to take Solvazinc.

Other medicines and Solvazinc

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

This is especially important if you are taking or have recently taken any of the following:

- copper supplements (see section 2 "Do not take Solvazinc....')
- tetracycline antibiotics (such as oxytetracycline or doxycycline) used to treat certain bacterial infections
- quinolone antibiotics (such as ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin) used to treat certain bacterial infections
- calcium salt preparations
- iron preparations
- penicillamine (used to treat rheumatoid arthritis, Wilson's disease, autoimmune hepatitis and cystinuria)
- trientine (used in the treatment of Wilson's disease)

Solvazinc with food and drink

Solvazinc should be taken after meals.

Pregnancy and breast-feeding

The safety of Solvazinc in human pregnancy is not known. Zinc has been shown to cross the placenta and is present in breast milk in females taking zinc supplements. Only take this product during pregnancy or while breast-feeding if your doctor has advised you to do so.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

Solvazinc is not expected to affect the ability to drive or use machines.

Solvazinc contains sorbitol (E420) and sodium

Each Solvazinc tablet contains 115.5mg of sorbitol (E420). 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 medicine contains 106mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 5.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Solvazinc

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. Solvazinc 45mg Effervescent Tablets should be taken orally.

The tablets should be dissolved in a glass of water and the solution swallowed.

Use in adults

The recommended dose for adults is one tablet, dissolved in water, once to three times daily after meals.

Use in children

The recommended dose for children is as follows: More than 30kg: one tablet, dissolved in water, once to three times daily after meals. 10-30kg: half a tablet, dissolved in water, once to three times daily after meals. Less than 10kg: half a tablet, dissolved in water, once daily after a meal.

You should not take Solvazinc for any longer than necessary. Your doctor, pharmacist or nurse will advise you on how long you should take Solvazinc.

If you take more Solvazinc than you should

If you take too many tablets, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining tablets with you to show the doctor.

If you forget to take Solvazinc

If you forget to take your tablets, take them as soon as you remember and then continue with the next dose as instructed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Solvazinc

To get the most benefit from Solvazinc, always finish the course of treatment recommended by your doctor or pharmacist.

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.

The following side effects have been reported:

- reduced copper levels, potentially leading to copper deficiency. Signs or symptoms of copper deficiency can include (for example) changes in the way you walk or problems with co-ordinating movements, a tingling or pricking sensation on the skin ('pins and needles' and/or numbness), reduced numbers of red and white blood cells.
- abdominal pain
- indigestion
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- stomach discomfort
- irritability
- headache
- lethargy (a feeling of weariness)

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 the Yellow Card

Scheme Website: <u>www.mhra.gov.uk/yellowcard</u> 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 Solvazinc

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

Store this product below 25°C. Store in the original packaging to protect the tablets from moisture.

Do not take Solvazinc if you notice that the pack or any of the tablets are damaged.

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 Solvazinc contains

The active substance is zinc (as zinc sulfate monohydrate). Each tablet contains 45mg of elemental zinc (which is equivalent to 125mg of zinc sulfate monohydrate). The other ingredients are: sorbitol (E420), mannitol (E421), sodium hydrogen carbonate, citric acid, saccharin sodium, povidone K25, sodium citrate and sodium carbonate anhydrous.

What Solvazinc looks like and contents of the pack

Solvazinc is a white, round, flat tablet with bevelled edges. When dissolved in water the solution is clear and colourless.

Each box of Solvazinc contains 90 effervescent tablets in three tablet containers of 30.

Each tablet container of Solvazinc also contains a small desiccant capsule contained within the cap of the container. This must not be swallowed.

Marketing Authorisation Holder

Galen Limited Seagoe Industrial Estate Craigavon BT63 5UA UK

Manufacturer

Almac Pharma Services Limited Almac House 20 Seagoe Industrial Estate Craigavon BT63 5QD UK

This leaflet was last revised in 11/2021