

Package leaflet: Information for the user

ZINCONIA® SYRUP

[Zinc acetate USP (as dihydrate)]

Read all of this leaflet carefully before your child starts 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, please ask your child's doctor, pharmacist or nurse.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What ZINCONIA® Syrup is and what it is used for
2. What you need to know before you use ZINCONIA® Syrup
3. How to use ZINCONIA® Syrup
4. Possible side effects
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6. Contents of the pack and other information

1. What ZINCONIA® Syrup is and what it is used for

ZINCONIA® Syrup is a mineral supplement used for the treatment of acute diarrhoea in children as an adjunct to oral rehydration. It contains zinc acetate (as dihydrate). Zinc acetate dihydrate is a source of zinc, which is an essential trace element and involved in a number of body enzyme functions.

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

You must talk to a doctor if you do not feel better or if you feel worse.

2. Before you take ZINCONIA® Syrup

Do not take ZINCONIA® Syrup if you

- if you are allergic (hypersensitive) to zinc or to any of the components of the formulation.
- 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 ZINCONIA[®] syrup if you suffer from kidney disease.
- If this applies to you it is important that you tell your doctor or pharmacist before taking ZINCONIA[®] syrup and they will decide what to do. It may still be safe for you to take syrup.

Taking other medicines

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 ZINCONIA[®]”)
- **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)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking ZINCONIA[®] Syrup with food and drink

You should take ZINCONIA[®] Syrup after meals.

Pregnancy and breast-feeding

The safety of ZINCONIA[®] Syrup 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

ZINCONIA[®] Syrup is not expected to affect the ability to drive or use machine.

3. How to take ZINCONIA[®] Syrup

Always take ZINCONIA[®] Syrup exactly as your doctor has told you. It should be taken orally.

Dose

Acute Diarrhoea:

- For children below 6 months: 2.5 ml daily for 10-14 days
- For children above 6 months: 5 ml daily for 10-14 days

If you take more ZINCONIA[®] Syrup than you should

If you take too large dosage, contact your nearest hospital casualty department or doctor immediately.

If you forget to take ZINCONIA[®] Syrup

If you forget to take your dose, take it 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 have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking ZINCONIA[®] Syrup

To get the most benefit from ZINCONIA[®] Syrup, 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, ZINCONIA[®] Syrup can cause side effects, although not everybody gets them.

Side effects with ZINCONIA[®] Syrup may include:

- reduced copper levels, potentially leading to copper deficiency
- 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top of the home page.

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

5. How to store ZINCONIA® Syrup

Store in a cool, dry place protected from light.
Keep out of 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 in the original packaging to protect the tablets from moisture.

Do not take ZINCONIA® Syrup if you notice that the bottle is 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 ZINCONIA® Syrup contains

Each 5 ml contains:

Zinc acetate USP (as dihydrate) equivalent to Elemental Zinc.....20 mg

Colour: Sunset Yellow FCF.

In a mentholated flavoured syrup base

What ZINCONIA® Syrup looks like and contents of pack

Amber-coloured bottle of 100 mL with measuring cap

Marketing Authorisation Holder

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