



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Zinc Sulphate Tablet + Oral Rehydration Salt

Zinc Sulphate Dispersible 20mg

Sodium Chloride 2.60g, Potassium Chloride 1.50g, Anhydrous Glucose 13.50g, Sodium Citrate 2.90g

Read this leaflet carefully before you start taking this medicine:

- You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Zinc Sulphate Tablet + Oral Rehydration Salt is and what it is used for
2. What you need to know before you use Zinc Sulphate Tablet + Oral Rehydration Salt
3. How to use Zinc Sulphate Tablet + Oral Rehydration Salt
4. Possible side effects
5. How to store Zinc Sulphate Tablet + Oral Rehydration Salt
6. Contents of the pack and other information

1. WHAT ZINC SULPHATE TABLET + ORAL REHYDRATION SALT IS AND WHAT IT IS USED FOR

Zinc Sulphate tablets and Oral Rehydration Salts (ORS) are used together to treat and prevent dehydration caused by diarrhoea, especially in children.

- ORS replaces the water and salts lost from the body during diarrhoea.
- Zinc helps to reduce the duration and severity of diarrhoea and helps prevent future episodes.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ZINC SULPHATE TABLET + ORAL REHYDRATION SALT

Check with your doctor, healthcare provider or pharmacist before giving Zinc Sulphate Tablet + Oral Rehydration Salt if the child is taking:

- Penicillamine (used to treat rheumatism and certain metabolic disorders [Wilson's disease, Cystinuria])
- Sodium valproate (used to treat seizures) or
- Ethambutol (used to treat tuberculosis)

Do not take this medicine:

- If you are allergic to any of the ingredients
- If you are severely dehydrated
- If you have a partial or full blockage (obstruction) of the bowel
- If you have phenylketonuria (this medicine contains aspartame, a source of phenylalanine)

Talk to your pharmacist or doctor:



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- If you have liver problems
- If you have kidney problems, including producing little or no urine
- If you have severe and persistent diarrhoea and sickness
- If you are unable to drink fluids, or are unable to keep fluids down
- If you have diabetes
- If you have an intolerance to some sugars

Other medicines and Zinc Sulphate + ORS

Please tell your doctor, healthcare provider or pharmacist if the child is taking or has recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.

Tell your doctor, healthcare provider or pharmacist if the child is taking:

- Certain antibiotics (medicines to treat bacterial infections): Tetracyclines, Quinolones, Cephalexin or Ceftibuten.
- Zinc may interfere with the uptake of these medicines, therefore, an interval of at least three hours should be allowed between intake of Zinc and any of these medicines.

Keep a list of all the medicines the child takes. Show this list to your doctor, healthcare provider or pharmacist before you start to give a new medicine like Zinc Sulphate Tablet + Oral Rehydration Salt.

Zinc Sulphate Tablet + Oral Rehydration Salt contains aspartame, a source of Phenylalanine. If your child suffers from a metabolic disorder called phenylketonuria, tell your doctor. He/she will decide if Zinc Sulphate Tablet + Oral Rehydration Salt can be given.

Zinc Sulphate Tablet + Oral Rehydration Salt with food and drink

Zinc Sulphate Tablet + Oral Rehydration Salt should be given between meals.

Pregnancy and breast-feeding

This medicine can be used if you are pregnant or breastfeeding. Inform your doctor or pharmacist if you are pregnant, breastfeeding, or are planning to get pregnant.

Driving and using machines

Zinc Tablet + ORS is not expected to have any effect on the ability to drive and use machines.

However, if you're experiencing dehydration, you might be tired and it's advisable to consult a healthcare professional before driving.



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3. HOW TO TAKE ZINC SULPHATE TABLET + ORAL REHYDRATION SALT

For Zinc Sulphate

Always give Zinc Sulphate Tablet + Oral Rehydration Salts exactly as your doctor has told you.

How much to give:

Children less than 6 months old: ½ tablet daily for 10 to 14 days.

Children 6 months to 5 years old: 1 tablet daily for 10 to 14 days.

Giving Zinc Sulphate Tablet

- It is recommended you give the doses between meals.
- Fill a teaspoon (5ml) with breast milk or with boiled and cooled water. Disperse the tablet (or half tablet) completely and get the child to swallow the entire mixture immediately.
- If the child vomits within 30 minutes of taking the dose, give another dose. If in doubt, talk to your doctor or healthcare provider.

For ORS:

Check the sachet to ensure it is not broken before use. If it is, do not take the sachet. Take with food.

Directions for use:

- Boil clean water.
- Allow the water to cool in a clean, uncontaminated container.
- Measure out 1 litre of the cooled water and add 1 sachet of Fidson ORS
- Stir well until the powder is completely dissolved.
- Administer the solution to the child as needed
- Use the prepared solution within 24 hours; any unused portion should be discarded.

Age	How many	How often to take them
Infants and Children 1 to 12 years	1–2 litres (5-10 glasses) in a day	After each stooling episode
Adults, the elderly and children over 12 years	2–4 litres (10-20 glasses) in a day	After each stooling episode

Infants under 1 year: Do not give this medicine unless a doctor tells you to. Follow your doctor's instructions and ask your pharmacist if you need more information. If needed stop all solid and liquid feeds. Over the first 24 hours give one to one and a half (1 – 1½) times the normal feed volume that your baby takes at each feed.

Breastfed infants: Give this medicine at normal feed times only. Then breastfeed until the infant is no longer hungry.



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Bottle fed infants: Stop all feeds. Give this medicine at normal feed times only.

- As diarrhoea improves re-introduce normal diet.
- Do not take or give more than the amount recommended above.
- Do not take this medicine for more than 24 to 48 hours.
- If your diarrhoea does not go away within 24 to 48 hours talk to your doctor.

Use ORS for the full prescribed length of time, even if your symptoms quickly improve.

If you are given more Zinc Sulphate + Oral Rehydration Salt than you should

If you accidentally give too many tablets or ORS solution talk to your doctor or healthcare provider at once, or go to your nearest emergency unit. The child may require medical attention. Remember to take the medicine with you and show it to the doctor or the staff of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

If you forget to take Zinc Sulphate Tablet + Oral Rehydration Salt

Try to make sure that you do not miss any dose. However, if you do forget to give a dose, give the missed dose as soon as you realize that you have forgotten it unless there is less than 6 hours until the next dose.

If you stop giving Zinc Sulphate Tablet + Oral Rehydration Salt

Do not stop giving the medicine unless your doctor or healthcare provider tells you to. Always follow the instructions carefully and complete the course of medication.

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

4. POSSIBLE SIDE EFFECTS

Zinc Sulphate

Like all medicines, Zinc Sulphate can cause side effects although not everyone gets them.

The most reported side effects (greater than 1 in 10 patients treated)

- Vomiting
- Regurgitation

In most cases vomiting or regurgitation occurred shortly after administration of the first dose (within 10 minutes) and was not recurrent.

Frequency not known (estimates for these effects are not available):



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- Stomach pain
- Dyspepsia

If the child gets side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

Oral Rehydration Salt

This medicine is not expected to cause any side effect.

Get emergency medical help if you have signs of any side effects or allergic reactions: hives, difficult breathing, swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- Fever, chills, sore throat, mouth sores, light-headedness
- Seizure
- Increased pressure inside the skull--severe headaches, ringing in your ears, dizziness, nausea, vision problems, pain behind your eyes.

5. HOW TO STORE ZINC SULPHATE TABLET + ORAL REHYDRATION SALT

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What ZINC SULPHATE TABLET + ORAL REHYDRATION SALT contains

Each tablet of Zinc Sulphate Tablet contains 20mg of Zinc Sulphate.

Each ORS Sachet contains: Sodium Chloride 2.60g, Potassium Chloride 1.50g, Anhydrous Glucose 13.50g, Sodium Citrate 2.90g.

What ZINC SULPHATE TABLET + ORAL REHYDRATION SALT looks like and contents of the pack

1 x10 blister of Zinc Sulphate Tablets and 2 sachets of 20.5 g Oral Rehydration Salts (ORS)

SUPPLIER AND MANUFACTURER

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