

Zinc (as sulfate monohydrate) 20 mg
Tablets (Macleods Pharmaceuticals
Ltd), DI005

WHOPAR Part 3

March 2017

Section 6 updated: May 2024

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zinc (as sulfate) Dispersible Tablets 20 mg¹
Zinc (as sulfate monohydrate) 20 mg Tablets

Read all of this leaflet carefully before start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor healthcare provider or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If the child has side effects and they become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

In this leaflet:

1. What Zinc (as sulfate) Dispersible Tablets 20 mg is and what it is used for
2. Before you give Zinc (as sulfate) Dispersible Tablets 20 mg
3. How to give Zinc (as sulfate) Dispersible Tablets 20 mg
4. Possible side effects
5. How to store Zinc (as sulfate) Dispersible Tablets 20 mg
6. Further information

1. WHAT ZINC (AS SULFATE) DISPERSIBLE TABLETS 20 MG IS AND WHAT IT IS USED FOR

Zinc (as sulfate) Dispersible Tablets 20 mg contains zinc. In the body, a small quantity of zinc (a so-called 'trace element') is essential for many different processes e.g. the ability to fight off infection. Zinc also prevents the growth of bacteria that can cause diarrhoea.

Zinc (as sulfate) Dispersible Tablets 20 mg is used for treating acute and persistent diarrhoea in infants and children aged up to 5 years.

This product is intended for use in children. Safety information on its use in adults is also provided.

2. BEFORE GIVING ZINC (AS SULFATE) DISPERSIBLE TABLETS 20 MG

Taking other medicines

Keep a list of all the medicines the child takes, or has recently taken, including medicines obtained without a prescription, vitamins and herbal medicines. Show this list to your doctor, healthcare provider or pharmacist before you start to give a new medicine like Zinc (as sulfate) Dispersible Tablets 20 mg.

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

- certain medicines for treating bacterial infection including cefalexin, cefitibuten, quinolones (e.g. ciprofloxacin and norfloxacin) and tetracyclines (e.g. oxytetracycline and tetracycline)
- penicillamine, which is used to treat rheumatism and certain metabolic disorders such as Wilson's disease and cystinuria

It is important to take zinc at least 3 hours before or 3 hours after taking these medicines because zinc can reduce the effect of these medicines or the medicines can reduce the effect of zinc.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Zinc (as sulfate) Dispersible Tablets 20 mg contains aspartame, a source of phenylalanine. Tell your doctor or healthcare provider if your child suffers from a metabolic disorder called phenylketonuria. The doctor or healthcare provider will decide if Zinc (as sulfate) Dispersible Tablets 20 mg can be given.

Giving Zinc (as sulfate) Dispersible Tablets 20 mg with food and drink

Zinc (as sulfate) Dispersible Tablets 20 mg should be given between meals.

Pregnancy and breast-feeding

Take advice from the doctor or healthcare professional about taking Zinc (as sulfate) Dispersible Tablets 20 mg if the woman is pregnant or might be pregnant.

Also, if a mother wants to breastfeed her baby, her doctor or healthcare provider should be asked for advice about taking Zinc (as sulfate) Dispersible Tablets 20 mg.

Driving and using machines

Zinc (as sulfate) Dispersible Tablets 20 mg does not have any effect on the ability to drive and use machines.

3. HOW TO GIVE ZINC (AS SULFATE) DISPERSIBLE TABLETS 20 MG

Always give Zinc (as sulfate) Dispersible Tablets 20 mg exactly as your doctor or healthcare provider has told you.

Ask your doctor, healthcare provider or pharmacist if you have any questions about this medicine.

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 (as sulfate) Dispersible Tablets 20 mg □

It is recommended you give the doses between meals.

- Fill a teaspoon (5 ml) with either breast milk or boiled and cooled water. Place the tablet (or half tablet) in the liquid. As soon as the tablet has dispersed completely get the child to swallow all the mixture.
- If the child vomits within 30 minutes of taking the dose, give another dose. If in doubt, talk to your doctor or healthcare provider.

If the child has taken too many tablets of Zinc (as sulfate) Dispersible Tablets 20 mg

If the child has accidentally taken too many tablets, 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 give Zinc (as sulfate) Dispersible Tablets 20 mg

If you miss giving a dose, give the missed dose as soon as possible. However, do not give the missed dose if the next dose is due in less than 6 hours.

If you stop giving Zinc (as sulfate) Dispersible Tablets 20 mg

Do not stop giving the medicine unless your doctor or healthcare provider tells you to. Follow the instructions for giving the medicine and complete the course.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zinc (as sulfate) Dispersible Tablets 20 mg can cause side effects, but not everybody gets them.

Very common side effects (which affect more than 1 person in every 10 who take this medicine):

- Vomiting
- Regurgitation (bringing up food that has been swallowed)

In most cases vomiting or regurgitation occurred within 10 minutes of the first dose and did not occur again.

Other side effects that may occur (but it is not known how frequently they occur):

- Stomach pain
- Indigestion or heartburn (dyspepsia)

If the child has side effects which become serious or if you notice any side effects not listed in this leaflet, tell your doctor, healthcare provider or pharmacist.

5. HOW TO STORE ZINC (AS SULFATE) DISPERSIBLE TABLETS 20 MG

- Keep out of the reach and sight of children.
- Do not store above 30°C. Protect from light and moisture. Store tablets in blisters in the provided carton.
- Do not use Zinc (as sulfate) Dispersible Tablets 20 mg after the expiry date stated on the blister and carton unit. The expiry date refers to the last day of that month.
- Medicines should not be disposed of in waste water or household waste. This helps protect the environment. Return any unused tablets to your pharmacist.

6. FURTHER INFORMATION

What Zinc (as sulfate) Dispersible Tablets 20 mg contains the active substance is zinc (as sulfate monohydrate).

The other ingredients are:

Aspartame
Microcrystalline cellulose
Colloidal silicon dioxide
Crospovidone
Trusil orange ASV flavour
Magnesium stearate

What Zinc (as sulfate) Dispersible Tablets 20 mg looks like and contents of the pack

White to off-white, circular flat, bevelled, uncoated, flavoured tablet with break-line on one side and plain surface on the other side.

PVC/ PVdC Alu blister of 10 tablets, such 10 blisters in a carton along with the pack insert.

Alu/Alu blister of 7 tablets. Pack size: 1 x 7 Tablets; 10 x 10 Tablets.

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Tablets (Macleods Pharmaceuticals
Ltd), DI005

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For any information about this medicinal product, please contact the supplier:

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal>