

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[DI013 trade name][†]
Zinc

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

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- 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 seem to be the same as your child's.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [DI013 trade name] is and what it is used for
2. What you need to know before you give [DI013 trade name] to your child
3. How to give [DI013 trade name]
4. Possible side effects
5. How to store [DI013 trade name]
6. Contents of the pack and other information

1. What [DI013 trade name] is and what it is used for

[DI013 trade name] is used for treating acute and persistent diarrhoea in infants and children aged up to 5 years.

[DI013 trade name] 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.

2. What you need to know before you give [DI013 trade name] to your child

Do not give [DI013 trade name]

- if your child is allergic (hypersensitive) to zinc sulfate or any of the other ingredients of this medicine (listed in section 6);
- if your child has copper deficiency.

Talk to your health care provider if this applies to your child.

Warnings and precautions

Talk to your health care provider if your child suffers from kidney disease.

If this applies to your child, it is important that you tell your health care provider before giving [DI013 trade name] to your child, and they will decide what to do. It may still be safe for your child to take [DI013 trade name].

Other medicines and [DI013 trade name]

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 health care provider or pharmacist before giving [DI013 trade name] to your child.

In particular, tell your health care provider if the child is taking:

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- copper supplements
- certain medicines for treating bacterial infection including cefalexin, ceftibuten, quinolones (e.g. ciprofloxacin and levofloxacin) 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
- trientine (used in the treatment of Wilson's disease)
- calcium salt preparations
- iron preparations

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.

[DI013 trade name] with food and drink

[DI013 trade name] should be given between meals.

Pregnancy and breast-feeding

Take advice from your health care provider about taking [DI013 trade name] if you are pregnant or might be pregnant.

Zinc is present in breast milk. Ask your health care provider for advice about taking [DI013 trade name] while breast-feeding.

Driving and using machines

[DI013 trade name] is not expected to affect the ability to drive and use machines.

Other ingredients of [DI013 trade name]

This medicine contains aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to give [DI013 trade name]

Always give [DI013 trade name] to your child 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 [DI013 trade name]

- 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 health care provider.

If the child has taken too many tablets of [DI013 trade name]

If the child has accidentally taken too many tablets, talk to your doctor or health care 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 [DI013 trade name]

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 [DI013 trade name]

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

4. Possible side effects

Like all medicines, [DI013 trade name] 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

Common side effects (which affect up to 1 in every 10 who take this medicine):

- Regurgitation (bringing up food that has been swallowed)

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

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

- Reduced copper levels, potentially leading to copper deficiency
- Stomach pain
- Stomach irritation
- Indigestion or heartburn (dyspepsia)
- Nausea (feeling sick)
- Irritability
- Headache
- Lethargy (lack of energy)

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

Reporting of side effects

If your child gets any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help improve understanding about the safety of this medicine.

5. How to store [DI013 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Protect from moisture and light. Store tablets in blisters in the provided carton.

Do not use this medicine after the expiry date stated on the carton or blister after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [DI013 trade name] contains

- The active ingredient is zinc (as sulfate monohydrate) 20 mg.
- The other ingredients of [DI013 trade name] are microcrystalline cellulose, maize starch, aspartame, colloidal silicon dioxide, vanilla flavour and magnesium stearate

What [DI013 trade name] looks like and contents of the pack

[DI013 trade name] is a white to off-white coloured, round-shaped, flat, dispersible tablet, one face is plain and the other face has a breakline. The tablet may have brown specks.

[DI013 trade name] is available in a white, opaque PVC/PVdC-aluminium blister. Each blister strip contains 10 tablets, such 10 blisters are packed in a paper board carton along with the patient information leaflet

Supplier

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

This leaflet was last revised in January 2022.

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>