

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.

Information for the patient

[DI011 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 [DI011 trade name] is and what it is used for
2. What you need to know before you give [DI011 trade name] to your child
3. How to give [DI011 trade name]
4. Possible side effects
5. How to store [DI011 trade name]
6. Contents of the pack and other information

1. What [DI011 trade name] is and what it is used for

[DI011 trade name] is used for treating acute and persistent diarrhoea in infants and children aged up to 5 years.

[DI011 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 [DI011 trade name] to your child

Do not give [DI011 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 [DI011 trade name] to your child, and they will decide what to do. It may still be safe for your child to take [DI011 trade name].

Other medicines and [DI011 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 [DI011 trade name] to your child.

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

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

- 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.

[DI011 trade name] with food and drink

[DI011 trade name] should be given between meals.

Pregnancy and breast-feeding

Take advice from your health care provider about taking [DI011 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 [DI011 trade name] while breast-feeding.

Driving and using machines

[DI011 trade name] is not expected to affect the ability to drive and use machines.

Other ingredients of [DI011 trade name]

This medicine contains 46.43 mg aspartame in each dispersible tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to give [DI011 trade name]

Always give [DI011 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 [DI011 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 [DI011 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 [DI011 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 [DI011 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, [DI011 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.

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 provide more information on the safety of this medicine.

5. How to store [DI011 trade name]

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

Do not store above 30°C. Protect from moisture.

Do not use this medicine after the expiry date stated on the label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any description of the visible signs of deterioration.

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 [DI011 trade name] contains

The active ingredient is zinc (as sulfate monohydrate).

The other ingredients of [DI011 trade name] are: microcrystalline cellulose, crospovidone, aspartame, sucralose, orange flavour, colloidal silicon dioxide and magnesium stearate

What [DI011 trade name] looks like and contents of the pack

[DI011 trade name] is a white to off-white, round, flat faced, bevel edge, uncoated, dispersible tablet, with a break-line on one side and debossed with 'C70' on the other side.

[DI011 trade name] is provided in a PVdC/PVC – Alu blister pack of 10 tablets. Such 1, 3 or 10 blisters are packed in a carton along with the patient information leaflet.

[DI011 trade name] is also provided in an Alu-Alu blister strip of 10 tablets. Such 1, 3 or 10 strips are packed in a carton along with the patient information leaflet.

Supplier and Manufacturer

Supplier

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

This leaflet was last revised in December 2020.

Section 6 updated in May 2023

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