

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[DI005 trade name][†]

Zinc

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- 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 [DI005 trade name] is and what it is used for
2. What you need to know before you take [DI005 trade name]
3. How to take [DI005 trade name]
4. Possible side effects
5. How to store [DI005 trade name]
6. Contents of the pack and other information

1. What [DI005 trade name] is and what it is used for

[DI005 trade name] is used for treating acute watery or persistent diarrhoea in children up to 10 years of age.

[DI005 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 take [DI005 trade name]

Do not give [DI005 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 [DI005 trade name] to your child, and they will decide what to do. It may still be safe for your child to take [DI005 trade name].

Other medicines and [DI005 trade name]

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

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 [DI005 trade name] to your child.

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.

[DI005 trade name] with food and drink

[DI005 trade name] should be given between meals.

Pregnancy and breast-feeding

Take advice from your health care provider about taking [DI005 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 [DI005 trade name] while breast-feeding.

Other ingredients of [DI005 trade name]

[DI005 trade name] contains aspartame. 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 take [DI005 trade name]

Always give [DI005 trade name] to your child exactly as your health care provider has told you.

Ask your health care provider if you have any questions about this medicine.

How much to give

Children less than 10 years old: 5 mg tablet daily for 10 to 14 days

Giving [DI005 trade name]

- It is recommended you give the doses between meals.
- To give this dose you will need:
 - 1 tablet of [DI005 trade name]
 - drinking water or breast milk
 - a 10-mL oral syringe
 - a container such as a bowl or a cup
 1. Use the oral syringe to measure 10 mL drinking water or breast milk into the container
 2. Add 1 tablet of [DI005 trade name] and stir gently until the tablet breaks down completely
 3. Use the oral syringe to measure 2.5 mL of the mixture and give to the child to take.
 4. Throw away any mixture remaining in the container.
- Repeat these steps every time you need to give the medicine.
- 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 [DI005 trade name]

If the child has accidentally taken too many tablets, talk to your 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 health care provider of the emergency unit. If you have run out of tablets, take the empty packaging along with you.

If you forget to give [DI005 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 [DI005 trade name]

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

4. Possible side effects

Like all medicines, [DI005 trade name] can cause side effects, but not everybody gets them.

Very common side effects (more than 1 in 10 people can get this side effect):

- Vomiting

Common side effects (up to 1 in 10 people can get this side effect):

- 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 (not known how often they can 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 health care provider.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [DI005 trade name]

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

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

Do not use this medicine after the expiry date stated on label after 'EXP'.

Do not use this medicine if you notice description of the visible signs of deterioration 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 [DI005 trade name] contains

- The active ingredient is zinc (as sulfate monohydrate).
- The other ingredients of [DI005 trade name] are aspartame, microcrystalline cellulose, colloidal silicon dioxide, crospovidone, trusil orange ASV flavour and magnesium stearate.

What [DI005 trade name] looks like and contents of the pack

White to off-white circular tablets. They are flat on the top and bottom with a bevelled edge. The tablets have a break line on one side and are plain on the other side.

The break line can be used to divide [DI005 trade name] into equal doses.

The tablets are packaged in clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing 10 tablets. Available in boxes of 10×10 tablets.

The tablets are also packaged in aluminium foil blister packs, each containing 7 or 10 tablets. Available in boxes of 1×7 or 10×10 tablets.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

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