

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

[DI010 trade name][†]

Zinc (sulfate)

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 [DI010 trade name] is and what it is used for
2. What you need to know before you take [DI010 trade name]
3. How to take [DI010 trade name]
4. Possible side effects
5. How to store [DI010 trade name]
6. Contents of the pack and other information

1. What [DI010 trade name] is and what it is used for

[DI010 trade name] is used for treating acute and persistent diarrhoea in infants and children aged up to 5 years.

[DI010 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 [DI010 trade name]

Do not give [DI010 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 [DI010 trade name] to your child, and they will decide what to do. It may still be safe for your child to take [DI010 trade name].

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

Other medicines and [DI010 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 [DI010 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.

[DI010 trade name] with food and drink

[DI010 trade name] should be given between meals.

Pregnancy and breast-feeding

Take advice from your health care provider about taking [DI010 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 [DI010 trade name] while breast-feeding.

Driving and using machines

[DI010 trade name] is not expected to affect the ability to drive and use machines.

Other ingredients of [DI010 trade name]

[DI010 trade name] also contains 3 mg aspartame in each 5 mL. 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.

[DI010 trade name] contains 10 mg sodium benzoate in each 5 mL, which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

[DI010 trade name] contains 3800 mg sorbitol in each 5 mL. Sorbitol is a source of fructose. If your health care provider has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your health care provider before you (or your child) take or receive this medicine. Sorbitol may also cause gastrointestinal discomfort and mild laxative effect.

3. How to take [DI010 trade name]

Always give [DI010 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 6 months old: 5 mL (1 teaspoonful) once daily for 10 to 14 days

Children 6 months to 5 years old: 10 mL (2 teaspoonfuls) once daily for 10 to 14 days

Giving [DI010 trade name]

- It is recommended you give the doses between meals.

- 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 much [DI010 trade name]

If the child has accidentally taken too much [DI010 trade name], 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 or the staff of the emergency unit. If you have run out of syrup, take the empty packaging along with you.

If you forget to give [DI010 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 [DI010 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, [DI010 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, please 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 [DI010 trade name]

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

Store below 30°C. Protect from light.

Do not use this medicine after the expiry date stated on the carton and bottle 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 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 [DI010 trade name] contains

- The active ingredient is 27.45 mg zinc sulfate monohydrate equivalent to 10 mg of zinc.
- The other ingredients of [DI010 trade name] are sodium benzoate, sorbitol solution, citric acid anhydrous, sodium citrate, aspartame, sodium saccharin, orange trusil flavour and purified water.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [DI010 trade name] looks like and contents of the pack

Clear transparent, orange- flavoured solution.

Amber type III glass bottle containing 60 mL of solution. The bottle is fitted with a plastic (LDPE) U-plug and closed with an aluminium cap. The product is supplied with a plastic (HDPE) graduated measuring spoon. Each bottle is packed in a carton.

Pack size: 60 mL

Supplier and Manufacturer

Supplier

PharmEvo (Pvt) Ltd.
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For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in September 2023

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