

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ZinCfant[®] 20mg*
Zinc (as sulfate monohydrate) 20 mg tablet

Read all of this leaflet carefully before you start giving 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 your child gets 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.

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1. What ZinCfant[®] 20mg is and what it is used for

ZinCfant[®] 20mg contains zinc. This is an essential mineral (a so called trace element) important for many different processes in the body, e.g. for the patient's ability to fight infection. Also, it has been shown to block the growth of diarrhoea causing bacteria.

ZinCfant[®] 20mg Tablets are used for the treatment of acute and persistent diarrhoea (loose stools) in infants and children up to 5 years of age.

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

2. Before giving ZinCfant[®] 20mg

Take special care with ZinCfant[®] 20mg

Check with your doctor, healthcare provider or pharmacist before giving ZinCfant[®] 20mg if the child is taking:

- Penicillamine (used to treat rheumatism and certain metabolic disorders [Wilson's disease, Cystinuria])
- sodium valproate (used to treat seizures) or
- ethambutol (used to treat tuberculosis)

* Trade names are not prequalified by WHO. This is under local drug regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Taking other medicines

Please tell your doctor, healthcare provider or pharmacist if the child is taking or has recently taken any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.

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

- certain antibiotics (medicines to treat bacterial infections): tetracyclines, quinolones, cephalixin or ceftibuten.
- Zinc may interfere with the uptake of these medicines, Therefore, an interval of at least three hours should be allowed between intake of zinc and any of these medicines.

Keep a list of all the medicines the child takes. Show this list to your doctor, healthcare provider or pharmacist before you start to give a new medicine like ZinCfant® 20mg.

ZinCfant® 20mg contains aspartame, a source of phenylalanine. If your child suffers from a metabolic disorder called phenylketonuria, tell your doctor. He will decide if ZinCfant® 20mg can be given.

Giving ZinCfant® 20mg with food and drink

ZinCfant® 20mg should be given between meals.

Pregnancy and Breastfeeding

Pregnancy

The safety of ZinCfant® 20mg in pregnancy has not been established.

Breastfeeding

The safety of ZinCfant® 20mg in breastfeeding has not been established.

The doctor or healthcare provider will advise.

Driving and using machines

ZinCfant® 20mg Tablet is not expected to have any effect on the ability to drive and use machines.

How to give ZinCfant® 20mg

Always give ZinCfant® 20mg Tablets exactly as your doctor has told you.

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 ZinCfant® 20mg

- It is recommended you give the doses between meals.
- Fill a teaspoon (5ml) with breast milk or with boiled and cooled water. Disperse the tablet (or half tablet) completely and get the child to swallow the entire mixture immediately.
- 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 you give more ZinCfant® 20mg than you should

If you accidentally give 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 ZinCfant® 20mg

Try to make sure that you do not miss any dose. However, if you do forget to give a dose, give the missed dose as soon as you realise that you have forgotten it unless there is less than 6 hours until the next dose.

If you stop giving ZinCfant® 20mg

Do not stop giving the medicine unless your doctor or healthcare provider tells you to. Always follow the instructions carefully, and complete the course of medication.

If you have any further questions on the use of this product, ask your doctor, healthcare provider or pharmacist.

3. POSSIBLE SIDE EFFECTS

Like all medicines, ZinCfant® 20mg can cause side effects, although not everybody gets them.

The most commonly reported side effects (greater than 1 in 10 patients treated)

- Vomiting
- Regurgitation

In most cases vomiting or regurgitation occurred shortly after administration of the first dose (within 10 minutes) and was not recurrent.

Frequency not known (estimates for these effects are not available):

- Stomach pain
- Dyspepsia

If the child gets side effects and they become serious or if you notice any other side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

4. HOW ZinCfant® 20mg IS STORED

- Keep out of the reach and sight of children
- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Do not use ZinCfant® 20mg tablets after the expiry date which is stated on the blister and carton unit. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. This will help protect the environment. Return any leftover tablets to your pharmacist.

5. FURTHER INFORMATION

What ZinCfant[®] 20mg tablets contain

- The active substance is zinc (as sulfate monohydrate).
- The other ingredients are:
Aspartame, colloidal anhydrous silica, ethyl vanillin, magnesium stearate, maize starch and microcrystalline cellulose.

What ZinCfant[®] 20mg tablets look like and contents of the pack

Round, ivory-white uncoated, dispersible tablets, flat on one side and with a score on the other side. The tablet can be divided into equal halves.

White PVC/PVDC-aluminium foil blister with green ink printing. Each blister strip contains 10 tablets, and 10 of such strips are packed in a packet.

Supplier and Manufacturer

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

This leaflet was last approved in 02/2013.

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