

FECONTIN-Z (CONTROLLED RELEASE TABLETS OF FERROUS GLYCINE SULPHATE AND ZINC SULPHATE WITH FOLIC ACID)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider or pharmacist.

What is in this leaflet?

1. What Fecontin-Z is and what it is used for?
2. What you need to know before you take Fecontin-Z?
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1. What Fecontin-Z tablets is and what it is used for?

Fecontin-Z belongs to a group of medicines called iron supplements. This medicine works by supplementing body's iron reserves. Iron is a mineral that is a component of haemoglobin, myoglobin and a number of enzymes necessary for body functions. Iron deficiency can affect muscle metabolism, heat production and catecholamine metabolism and has been associated with behavioural or learning problems in children. When the body does not get enough iron, it cannot produce the number of normal red blood cells needed to keep you in good health.

Fecontin-Z Tablets are commonly used to reduce the risk of iron deficiency anaemia, a condition that occurs due to inadequate iron intake or absorption in the body.

The combination of iron and folic acid promotes the healthy production of red blood cells.

Zinc present in Fecontin-Z helps to boost the immune system and support overall health.

Folic acid and Zinc in the tablets may help in maintaining healthy skin and hair.

2. What you need to know before you take Fecontin-Z tablets?

Do not take Fecontin-Z and tell your doctor if you:

- are **allergic** (hypersensitive) to the active substances, iron salts, or any of the other ingredients of this medicine.
- are receiving repeated **blood transfusions**.
- are receiving iron **intravenously**.
- have a disorder in which there is **excessive absorption and storage of iron** such as haemochromatosis, hemosiderosis, hemolytic anemia, in B₁₂ deficiency anemia without concomitant B₁₂ supplementation.

Warnings and precautions

Due to the risk of mouth ulceration and tooth discolouration, tablets should not be sucked, chewed or kept in the mouth but swallowed whole with water.

If you cannot follow this instruction or have difficulty swallowing, please contact your doctor.

Failure to respond to treatment may indicate other causes of anaemia and should be further investigated. You are advised to contact your doctor for the same.

This medicine is not recommended for children or elderly patients.

Talk to your doctor or pharmacist before taking Fecontin-Z if you have:

- **haemochromatosis** - a hereditary disorder in which excessive amounts of iron accumulate in the body tissues
- **haemolytic anaemia** - a blood disorder characterised by low number of red blood cells
- a blood disease (**haemoglobinopathy**)
- **red cell aplasia** - a blood disorder where there is no production of red blood cells
- **Vitamin B12 deficiency** or any other blood disorder
- **gastrointestinal disease**

Other medicines and Fecontin-Z:

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- tetracyclines (to treat infections)
- ciprofloxacin, norfloxacin, ofloxacin, Chloramphenicol (to treat infections)
- colestyramine
- antacids (containing magnesium or aluminium, medicines used to neutralise acidity, especially in the stomach)
- medicines containing zinc, calcium, phosphorus or trientine

- methyldopa (to treat high blood pressure)

- penicillamine (medicine used to treat rheumatoid arthritis)
- Amino salicylic acid (for treatment of infections, arthritis)
- levodopa (for Parkinson's disease)
- ascorbic acid (vitamin C)
- iron-binding agents such as phosphates, oxalates, phytates and components of tea, coffee, milk and eggs which can impair the absorption of iron
- bisphosphonates (such as alendronic acid or disodium etidronate) used generally for osteoporosis
- dimercaprol used for the treatment of acute poisoning by certain heavy metals
- thyroid hormones such as levothyroxine used for the treatment of an under active thyroid. Oral iron reduces the absorption of levothyroxine (thyroxine) thus should be taken at least 2 hours apart.

Pregnancy and breast-feeding

Use of any drug in the first trimester of pregnancy should be avoided if possible. Thus, administration of iron in the first trimester requires definite evidence of iron deficiency. This medicine is recommended for use during pregnancy (second trimester onwards) and whilst breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Fecontin-Z does not affect your ability to drive or operate machinery.

3. How to take Fecontin-Z Tablets?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet to be taken daily during pregnancy (2nd trimester onwards). Tablets should be swallowed whole and not chewed. Not to be taken with hot liquids.

This medicine is not recommended for children or elderly patients.

Your doctor or pharmacist can advise you on how long you should continue treatment.

If you take more Fecontin-Z tablets than recommended

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Fecontin-Z tablets

If you forget to take a dose, take the missed dose as soon as you remember. If your next dose is due within the next two hours, take a single dose straight away and skip the next. Do not take a double dose to make up for a forgotten dose.

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

If you stop taking Fecontin-Z tablets

You will probably take these tablets for a long time. Do not stop taking them unless your doctor tells you to, even if you feel better.

If you have any further questions on the use of these tablets, ask your doctor, pharmacist, or nurse.

4. Possible side effects?

Like all medicines, Fecontin-Z can cause side effects although not everybody gets them.

If you get any of the following serious side effects, contact your doctor straight away or seek emergency help immediately:

Allergic reactions, e.g., skin rashes, swelling of the face, lips, tongue or throat, breathlessness and/or collapse.

Fecontin-Z may also cause the following:

- Gastro-intestinal irritation (upset stomach)
- stomach -pain
- feeling sick (nausea) or being sick (vomiting)
- constipation (occasionally faecal impaction)

- diarrhoea
- blackening of the stools

Fecontin-Z Continus tablets are designed to reduce the possibility of gastro- intestinal irritation and associated complications.

Mouth ulceration (In case of incorrect use, when tablets are chewed, sucked or left in the mouth)

Elderly patients and patients with difficulty swallowing may also be at risk of ulceration of the throat, oesophagus (the tube that connects your mouth with your stomach) or bronchus (the major air passages of the lungs) if the tablet enters the airways.

Overdose and its treatment

Iron overdosage is dangerous, particularly in children, and requires immediate attention. Symptoms may include abdominal pain, vomiting, diarrhoea and hematemesis. In more severe cases, coma, convulsion, shock, metabolic acidosis etc. may be precipitated. Gastric lavage should be carried out in early stages, or if this is not possible, vomiting should be induced. Oral desferrioxamine and demulscents should be given. Chelating agents such as dimercaprol, penicillamine or edetic acid may be used if required. Symptomatic and supportive measures should be given as required.

The Continus release tablets may delay the absorption of iron and allow for more time for initiation of appropriate counter measures.

5. How to store Fecontin-Z Tablets?

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

Store at or below 30° C in a dry place, protected from light.

Do not use this medicine after the expiry date which is stated on the blister strip and carton.

The expiry date refers to the last day of that month.

6. Other information

What Fecontin-Z Tablets contains?

- Each film-coated tablet contains:
Ferrous Glycine Sulphate equivalent to 100 mg Ferrous Iron
(In a controlled release system).
Zinc Sulphate Monohydrate USP 61.8 mg
(In a controlled release system).
Folic Acid BP: 0.5 mg
Colour: Erythrosine Lake and Yellow Oxide of Iron
- The other ingredients are Hydroxyethylcellulose, Cetostearyl Alcohol, Purified Talc, Magnesium Stearate, Purified water, Diethyl Phthalate, Opadry OY-58900 white, Hydroxypropyl methylcellulose, Ethyl cellulose 10cps, Polyethylene Glycol, Opadry 02H55103 Red.

What Fecontin-Z tablets looks like and contents of the pack?

Fecontin-Z is red, round, biconvex, film-coated tablets.

Box of 100 Tablets (10x10's Blister strip)

Manufactured by:

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110

U.P., India

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