

**Patient Information Leaflet**

# **Feronia XT<sup>®</sup> Drops**

(Ferrous Ascorbate & Folic Acid Drops)

**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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**

1. What Feronia XT<sup>®</sup> Drops is and what it is used for
2. What you need to know before you take Feronia XT<sup>®</sup> Drops
3. How to take Feronia XT<sup>®</sup> Drops
4. Possible side effects
5. How to store Feronia XT<sup>®</sup> Drops
6. Contents of the pack and other information

**1. WHAT FERONIA XT DROPS IS AND WHAT IT IS USED FOR**

Feronia XT<sup>®</sup> Drops contains a form of iron called Ferrous ascorbate, and a form of vitamin B - Folic acid. Iron is usually found in foods and is necessary for the normal development of red blood cells. A lack of iron affects the development of the red blood cells and causes iron deficiency anaemia. Folic acid is used to treat anemia caused by folate deficiency.

Feronia XT drops is used to prevent or treat iron deficiency anaemia in children.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FERONIA XT DROPS**

Do not take medicine if:

- You are allergic to Feronia XT or any of the other ingredients of this medicine, or to any other medicine containing iron
- You have noticed blood in your urine

- You suffer from any form of anaemia, other than iron deficiency anaemia, or from any other condition where your body's iron is affected (your doctor will be able to advise you)
- You have bronze markings on your skin or you have been told that you have increased stores of iron in your tissues
- You are undergoing repeated blood transfusions
- You suffer from ulcerative colitis or any other inflammatory condition of the bowels.

Speak to your doctor if any of these apply to you before you take your medicine.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Feronia XT drops if:

- You suffer or have suffered from a peptic ulcer
- You have problems associated with narrowing of your intestine (stricture) or outpocketing of the inner layer of your intestine (diverticular disease)
- You have difficulty in absorbing certain sugars (glucose or galactose)
- You have had some or all of your stomach removed as this may make it difficult for you to absorb iron
- You have diabetes.

If any of these conditions apply to you, speak to your doctor before you take this medicine. Your doctor will want to watch you closely, and will advise you if any additional medicine is required to treat your condition.

### **Other medicines and Feronia XT drops**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

The effects of any of these medicines or of Feronia XT drops may change, particularly if you are taking:

- Certain medicines for treating infections (e.g. chloramphenicol, tetracyclines, ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, norfloxacin)
- Medicines containing zinc, calcium or magnesium salts
- Levothyroxine, used for thyroid gland problems
- Medicines used for a disease known as 'Parkinson's disease' (e.g. levodopa, entacapone).
- Methyl dopa, used for increase in blood pressure

- Antacids used to treat indigestion
- Penicillamine used in the treatment of rheumatoid arthritis.
- Colestyramine used to reduce cholesterol and fats in the blood.
- Medicines for bone diseases (bisphosphonates)
- Trientine, used for high copper levels in blood
- Dimercaprol, used for various metal poisonings
- Mycophenolate, used during change of organs (transplant).

### **Feronia XT drops with food and drink**

Feronia XT drops may be taken with meals. This may help to relieve any stomach related side effects. However, it is advisable not to take your medicine with tea, eggs or milk as this may reduce its effect.

### **3. HOW TO TAKE FERONIA XT DROPS**

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

It is important to take your medicine at the right time.

The label will tell you how much to take and how often.

The recommended dose is:

#### **Use in children**

For children and premature infants, your doctor will decide the dose, according to the age and weight of the child and infant.

#### **Prevention of iron deficiency:**

Paediatric population:

6-24 months of age: 1-2 ml/day

2-5 years of age: 2-3 ml/day

6-11 years of age: 3-6 ml/day

Older children: 6 ml/day

*Premature infants:* 0.5 ml/day. Iron supplementation in premature infants is only recommended in those of low birth weight who are solely breast fed.

#### **Treatment of iron deficiency:**

Paediatric population:

Full term infants and children: 3 to 6 mg elemental iron/Kg/day given in 2 to 3 divided doses.

Total daily dose should not exceed 180 mg elemental iron.

Your doctor will advise you on how long you should take the medicine, which is normally not more than six months. It is usually stopped three months after the anaemia has been corrected.

If you have to go to another doctor or to the hospital tell them you are taking Feronia XT drops.

**If you take more Feronia XT drops than you should:**

Contact your nearest hospital casualty department or doctor immediately. Take any remaining medicine and this leaflet with you so that the medical staff know exactly what you have taken.

Your medicine is very dangerous if too much is taken by young children and care should be taken to keep the medicine safely out of the reach of children.

**If you forget to take your Feronia XT drops:**

Do not take a double dose to make up for a forgotten dose.

Take your dose as soon as you remember. Then go on as before. If it is almost time for the next dose, then do not take the missed dose at all.

**If you stop taking Feronia XT drops:**

If you are having no problems with Feronia XT drops, do not stop taking it until your doctor tells you to.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Not known: frequency cannot be estimated from the available data

Other side effects may include:

- stomach discomfort
- pain in upper part of the stomach
- vomiting sensation
- difficulty in passing stools
- loose stools.

**Folic Acid**

Folate appears to be well-tolerated in recommended doses.

Erythema, urticaria, skin flushing, rash, itching, nausea, bloating, flatulence, cramps, bitter taste, and diarrhoea have been reported. The colour of the urine may become more intense.

Folic acid may mask the symptoms of pernicious, aplastic or normocytic anaemia caused by vitamin-B12 deficiency and may lead to neurological damage.

Also, you might find your stools are darker in colour after you have taken this medicine. This is quite commonly seen with all iron preparations and is normal.

If you use Feronia XT drops for a long time the sugar content may increase the risk of tooth decay. It may also result in blackish discolouration of the teeth. This can be reduced by daily brushing of the teeth.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the “Safety Reporting” located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

## **5. HOW TO STORE FERONIA XT DROPS**

- Important warning: contains iron.
- Keep this medicine out of the sight and reach of children, as overdose may be fatal.
- Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.
- If you have any of your medicine left after finishing your treatment, return it to your pharmacist.
- Do not use this medicine if the bottle is damaged or after the Expiry Date which is stated on the bottle after ‘Exp’. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **REMEMBER**

This medicine is for your baby. Never give it to anyone else. It may harm them, even if their symptoms are the same as yours.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

The active substances are Ferrous Ascorbate and Folic Acid.

Each 1 ml contain 10 mg ferrous ascorbate and 100 mcg folic acid.

**What Feronia XT drops looks like and contents of pack**

It is packed in 15 ml amber colored bottle.

**Marketing Authorisation Holder**

Zuventus Healthcare Ltd.,

Zuventus House, Plot Y2, CTS No.: 358/A2,

Near Nahur Railway Station,

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**This leaflet was last revised in October 2023.**