Package leaflet: Information for the patient

ZADA PHARMACEUTICALS

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 more 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 signs of illness 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.

FERZADA 100 mg chewable tablets
Dextriferon

What is in this leaflet

1. What FERZADA is and what it is used for
FERZADA contains the active substance iron, in the form of iron (III) hydroxide polymaltose complex. Iron is an essential element required for the oxygen-carrying capacity of haemoglobine (the red pigment in the blood cells) and of myoglobin (the red pigment in muscle tissue). In iron deficiency the contents of the pigment are decreased and, if the iron deficiency persists, iron deficiency anemia (low level of hemoglobin and depletion of red blood cells) will occur.
FERZADA is used in the treatment of iron deficiency in adults and adolescents above the age of 12.

2. What you need to know before you take FERZADA
Do not take FERZADA
·if you are allergic to the active substance or any of the other ingredients of this medicine(listed in section 6),
·if iron is overloaded in your body (e.g. hemochromatosis or hemosiderosis),
·if you have problems in uptake of iron in your body, (e.g. thalassemia),
·if you have anemia not caused by iron deficiency (e.g. haemolytic anemia – due to hemolysis, with abnormal breakdown of red blood cells – or megaloblastic anemia – a blood disorder with very large red blood cells).

Warnings and precautions
Talk to your doctor or pharmacist before taking **FERZADA**. Anemia can be caused by infections and tumors. Iron cannot be used until recovery of the primary disease. Talk to your doctor if you have a chronic infection or tumor.
During therapy with **FERZADA** stools may be colored dark, which is harmless. Iron-based preparations can cause poisoning, especially in children. Talk to your doctor if you take iron supplementation.

Children
FERZADA is not intended for use by children aged 12 years old and younger.

Other medicines and FERZADA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not take iron orally and intravenously (drip in a vein) at the same time. The uptake or oral iron is significantly decreased when taken together. No other changes of effects when taken together with other medicines are likely to occur.

FERZADA with food and drink
FERZADA is taken preferably with food, for better absorption.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Use of **FERZADA** during pregnancy is not likely to cause any adverse effects for the fetus or the woman. Use of **FERZADA** during breast-feeding is not likely to cause any adverse effects for the child.

Driving and using machines
FERZADA has no influence on the ability to drive and use machines.

FERZADA contains sorbitol .If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Sorbitol can cause mild laxative effect.

FERZADA contains mannitol. Mannitol can cause mild laxative effect.

3. How to take FERZADA
Always take this medicine exactly as your doctor has told you. Check with your doctor, if you are not sure. Depending on how serious your condition is, your doctor will decide on your individual dose.
The recommended dose is:
Children
FERZADA is not intended for use by children aged 12 years old and younger.
Adults and adolescents over 12 years:
Iron deficiency:
1 to 3 tablets daily depending on the severity of the iron deficiency.
During treatment your doctor will check your response to the treatment by blood tests, and adjust the dose if necessary.
Duration of treatment
Duration of treatment may vary depending on the condition for which you take **FERZADA**. Your doctor will therefore discuss with you how long you need to take it.
Administration
You should take the tablets with a glass of water. It is recommended to take the tablets during or immediately after a meal for better absorption. **FERZADA** chewable tablets can be chewed or swallowed whole.

If you take more FERZADA than you should
Iron-based preparations can cause poisoning, especially in children.
Symptoms of overdose include: vomiting, vomiting of blood, abdominal pain, lethargy (asymptom that causes you to feel sleepy or fatigued), acute liver failure, coagulopathy (a condition in which the blood's ability to clot is impaired), kidney injury, metabolic acidosis (a clinical disturbance characterized by an increase in plasma acidity), shock, scars in stomach and pyloric stricture (narrowing of the opening from the stomach to the first part of the small intestine). Acute liver failure and cardiovascular collapse are the main causes of death due to iron overdose.
Contact your doctor or pharmacist if you have taken too much of this medicine, or if a child has taken it by mistake.

If you forget to take FERZADA
Take your next dose as scheduled. Do not take a double dose to make up for a forgotten tablet.

If you stop taking FERZADA
For the treatment to be successful, **FERZADA** should be taken regularly at the dose prescribed by your

doctor. Do not change, interrupt or stop the treatment without consultation.
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.
While you are taking **FERZADA**, you may experience one or more of the following side effects with the following frequencies:
Very common (may affect more than 1 in 10 people):
·dark colouration of the stool
Common (may affect up to 1 in 10 people):
·diarrhea,
·nausea,
·digestive disorders
Uncommon (may affect up to 1 in 100 people):
·vomiting,
·constipation,
·abdominal pain,
·discoloration of teeth
·rash,
·itching,
·headache

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

5. How to store FERZADA
Do not store above 25°C. Store in the original package.
Keep out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

6. Contents of the pack and other information
What FERZADA contains
The active substance is iron (III) hydroxide polymaltose complex. Each tablet contains iron (III) hydroxide polymaltose complex equivalent to 100 mg iron.
The other ingredients are: mannitol, sorbitol, povidone, saccharin sodium, vanilla, magnesium stearate.

What FERZADA looks like and contents of the pack
Box of 30 tablets of 100 mg dextriferon in blister pack (3 bllisters x 10 tablets).

Marketing Authorisation Holder and Manufacturer
ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

Date and number of marketing authorization:
FERZADA, chewable tablets:
Number: 04-07.3-2-6437/16 **Date:** 27.12.2016.

This leaflet was last revised in 5 July 2017