

Package leaflet: Information for the user

Niferex 100mg gastro-resistant capsules, hard iron (Fe ²⁺)

[For medicines available only on prescription]

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 your 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. See section 4.

[For medicines available without a prescription]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to doctor if you do not feel better or if you feel worse.

<[To be completed nationally]>

What is in this leaflet:

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

1 What X is and what it is used for

X is a form of iron that can be taken by mouth to treat or prevent iron deficiency. Iron is essential for transport of oxygen and for energy transfer in the body. The capsules are called gastro-resistant because they do not release their contents in the stomach. They deliver the iron to your gut where it can be absorbed.

Niferex is used for the treatment of iron deficiency.

2 What you need to know before you take X

Do not take X

- if you are allergic to the iron complex or any of the other ingredients of this medicine (listed in section 6).

- if you have a narrowing in your oesophagus.
- if you suffer from a hereditary iron storage disease (haemochromatosis)
- if you suffer from iron overload diseases (chronic haemolysis, thalassaemia, other haemoglobinopathias)
- if you suffer from iron utilization disorders (eg sideroachrestic anaemia, lead anaemia)
- if you receive repeated blood transfusions

Children

- Children younger than 6 years must not take X.
- Children 6 years and older with a body weight below 20 kg must not take X.

Warnings and precautions

Talk to your doctor or pharmacist before taking X.

Special caution in X intake is needed.

- if you already suffer from diseases of the digestive system such as chronic inflammatory bowel disease, esophageal and intestinal narrowing, protuberances of intestine (diverticles), gastritis, stomach and intestinal ulcers.
- if you suffer from chronic renal disease requiring erythropoietin, iron should be given intravenously as oral iron is poorly absorbed in uraemic individuals.
- if you suffer from impaired hepatic function and/or suffer from alcoholism.
- if you are an elderly person with blood or iron loss of unknown origin. In this case the cause of anaemia / the source of haemorrhage has to be carefully examined.
- Your teeth may become discoloured during treatment with X. (This discolouration may disappear when you stop taking X. If it does not, you may have to remove it with abrasive toothpaste or have professional dental cleaning).

Children

Take special care when given to children, as an overdose may lead to poisoning in children.

Other medicines and X

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

Increase in efficacy and possible increase of side-effects

- Pain relievers (analgesics) and antirheumatics (e.g. salicylates and phenylbutazone): may worsen an irritation of the mucous membrane of the stomach caused by X.
- Intravenous treatment of iron concomitantly with oral iron treatment may lead to low blood pressure (hypotension) or even collapse because of too fast iron release and possible overload. This combination is not recommended.

Decrease in efficacy and possible increase of side-effects

- Certain antibiotics (tetracyclines) or medicines (bis-phosphonates) used to treat weakened bones (osteoporosis): if you are also taking X both the absorption of iron and the absorption of the tetracyclines or bis-phosphonates are reduced. This means the effects of all these medicines will be reduced. Ask your doctor if you need to increase the dose of these medicines.
- Drugs containing calcium, magnesium or aluminium, e.g. antacids, calcium and magnesium salts for substitution: these medicines reduce or prevent you from absorbing the iron in X. You may need to increase the amount of X you take.
- Medicines for arthritis, such as penicillamine and oral gold compounds, medicines for Parkinson's disease, such as L-methyldopa and levodopa and L-thyroxin, used to treat thyroid deficiency: these medicines are less well absorbed when you are taking X with iron. You should ask your doctor if you need to increase your dose of these medicines.
- Treatments for infection (antibiotics) in the group known as fluoroquinolones, such as ciprofloxacin, levofloxacin, norfloxacin and ofloxacin: iron greatly reduces the amount of these drugs that you absorb. You should tell your doctor you are taking X before starting a course of these medicines.

The time interval between the administration of X and any of the above-mentioned drugs should be at least 2 hours.

The time between administration of X and tetracyclines other than doxycycline (see below) should be at least 3 hours.

- You should not take doxycycline and X together, as doxycycline may inhibit the absorption and circulation of X.

Other possible side-effects

- A dark coloration of the stool that is not resulting from hidden bleeding in your gut may occur.
- X contains Vitamin C, which may cause the presently common tests for traces of blood in the stool to be false-negative.

Niferex with food and drink

Niferex should not be taken with food. Substances contained in vegetable foods (e.g. cereals and vegetable) can form complexes with iron (e.g. phytates, oxalates and phosphates). These complexes stop you absorbing the iron. The ingredients of coffee, tea, milk and cola drinks can also reduce the uptake of iron into the blood.

The time between the intake of these compounds and X should be at least two hours

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 or pharmacist for advice before taking this medicine.

There are no known risks when using X during pregnancy and breast feeding.

Driving and using machines

Niferex should not affect your ability to drive or use machinery.

X contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 capsule, that is to say essentially 'sodium-free'

3 How to take X

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

Do not take more than 5 mg of X for every kilo you weigh. For example if you weigh 60kg, the maximum daily dose would be $5 \times 60 = 300$ mg (three capsules).

Unless otherwise prescribed by your doctor, the usual dose is:

Children from age 6 years (from a body weight of 20 kg), adolescents and adults

Bodyweight (kg)	Capsules per intake	Frequency of intake	Total Fe ²⁺ dose (mg)
≥ 20	1	1 time daily	100

Adolescents from age 15 years (from a body weight of 50 kg) and adults

In adults and adolescents from age 15 years the following dosage is recommended in cases of pronounced iron deficiency at the beginning of therapy:

Bodyweight (kg)	Capsules per intake	Frequency of intake	Total Fe ²⁺ dose (mg)
50 - < 60	1	2 times daily	200
≥ 60	1	2 - 3 times daily distributed over the day	200 - 300

Children and adolescents

X must not be used (at a body weight of less than 20 kg) (see Section 2) in children aged under 6 years.

Children from 6 years (minimum 20 kg body weight) can be given 1 capsule daily. For further dosages see table.

Mode of Administration

Take X capsules with sufficient water DO NOT chew the capsule. The capsules are to be taken at sufficient intervals from meals (for instance, on an empty stomach in the morning or between two principal meals), because absorption can be reduced by ingredients of food.

Note

If you can't swallow capsules or don't like to, you can empty out the capsule and swallow the contents. To do this, carefully pull the two halves of the capsule apart over a bowl. Gently shake out the content, scoop it up with a teaspoon and swallow it. You should drink some water after swallowing the capsule content.

Duration of treatment

Your doctor will decide how long you need to keep taking X.

The treatment should continue until you reach normal blood iron levels, this requires usually 10 to 20 weeks, or longer in case of persisting underlying condition.

Treatment duration in prevention of iron deficiency varies depending on the situation (pregnancy, blood donation, chronic haemodialysis, and planned autologous transfusion).

If you take more X than you should

After an intentional or accidental overdose, the symptoms described in section 4 "Possible side effects" are more likely to occur and will be more severe.

If you have taken too much X, you should inform your doctor **immediately**.

Overdose can cause poisoning especially in children.

Iron poisoning can show symptoms such as restlessness, stomachache, nausea, vomiting and diarrhoea are observed. The faeces show a tarry coloration, the vomit can contain blood. Shock, acidosis (too much acid in the body) and coma can develop. Death can occur after convulsions, Cheyne-Stokes breathing (abnormal pattern of breathing, characterized by alternating periods of shallow and deep breathing), coma and pulmonary oedema.

If you forget to take X

Do not take a double dose to make up for a forgotten dose. If you have forgotten one or several doses of X, just keep taking it for a little longer.

If you stop taking X

You don't need to take any special precautions before stopping treatment with X.

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

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them. X may in single cases (for which the frequency cannot be calculated) cause a severe allergic (anaphylactic) reaction. If you experience severe rash, itching and difficulty in breathing you must seek urgent medical advice.

Common side effects (affects 1 to 10 users in 100)

- stomach or gut (abdominal) discomfort
- heartburn
- being sick (vomiting)
- runny stools (diarrhoea)
- nausea
- constipation
- dark coloured stools (faeces)

Rare side effects (affects 1 to 10 users in 10,000)

- tooth discolouration (see also take special care with X under Section 2)
- Hypersensitivity (e.g. skin manifestations, exanthema, rash, urticaria)

Not known (frequency cannot be estimated from the available data)

- Abdominal pain and abdominal pain upper
- Gastrointestinal bleeding
- Tongue discolouration
- Discolouration of the inside of the mouth

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. You can also report side effects directly the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store X

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

Do not use this medicine after the expiry date, which is stated on the outer carton and the blister. The expiry date refers to the last day of that month.

Do not store above 25°C.

6. Contents of the pack and other information

What X contains

The active substances is ferrous(II)-glycine-sulphate complex. One capsule contains: 567.7 mg Ferrous (II) glycine-sulphate complex (is equivalent to 100 mg Fe ²⁺).

The other ingredients are:

Pellets with ferrous(II)-glycine-sulphate complex:

Ascorbic acid, microcrystalline cellulose, hypromellose, hydroxypropylcellulose, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30% (Eudragit L30 D-55) (contains methacrylic

acid-ethyl acrylate copolymer (1:1), sodium laurilsulfate, polysorbate 80), acetyltriethyl citrate, talc

Capsule shell:

-body: gelatin, titanium dioxide (E 171), red iron oxide (E 172), yellow iron oxide (E 172)

-cap: gelatin, titanium dioxide (E 171), red iron oxide (E 172), black iron oxide (E 172)

What X looks like and contents of the pack

X is a hard gastro-resistant gelatine capsule approximately 21.7 mm x 7.5 mm in size, with a chocolate-brown, opaque, unprinted cap and an orange, opaque, unprinted body. It contains grey-brownish, enteric, coated pellets.

X is available in packs containing 30, 50, 90, 100 and 500x1 gastro-resistant capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Aesica Pharmaceuticals GmbH

Alfred-Nobel-Str. 10

40789 Monheim

Germany

Phone: 02173/48-0

Fax: 02173-18-1608

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark: Niferex

Spain: Ferro Sanol

Greece: Ferro Sanol Duodenal

Italy: Niferex

Norway: Niferex

Poland: Obsidan

Sweden: Niferex

This leaflet was last revised in December 2025.

<[To be completed nationally]>

<Other sources of information>

<Detailed information on this medicine is available on the website of {name of Member State Agency (link)}>