

NEW ZEALAND CONSUMER MEDICINE INFORMATION

FERODAN

***Ferrous sulfate heptahydrate oral solution 30 mg/mL
(equivalent to 6 mg/mL elemental iron)***



What is in this leaflet

Please read this leaflet carefully before you start taking FERODAN.

This leaflet answers some common questions about FERODAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking FERODAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FERODAN is used for

FERODAN is used to prevent or treat iron deficiency anaemia. You should only take iron on advice from your doctor or pharmacist.

FERODAN contains the active ingredient ferrous sulfate which is a form of iron.

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.

Your doctor or pharmacist may have advised you to take FERODAN for another reason.

Ask your doctor or pharmacist if you have any questions about

why you were advised to take this medicine.

This medicine is available only from your pharmacy.

Before you take FERODAN

When you must not take it

Do not take FERODAN if you have an allergy to:

- any medicine containing iron (ferrous sulfate)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take FERODAN if:

- you have haemochromatosis (a disorder in which there is too much iron in your blood)
- you are receiving repeated blood transfusions
- you are receiving iron intravenously
- you are unable to absorb iron (e.g. due to an inflamed bowel disease).

Do not give FERODAN to a child under the age of 2 years unless your doctor has told you to.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

It is important to exclude any underlying cause of the anaemia such as heavy periods, or blood loss in the stool or urine.

Tell your doctor or pharmacist if:

- you suffer from any disease which affects your stomach and intestines (gastro-intestinal tract, such as a stomach ulcer or ulcerative colitis)
- you suffer from any form of anaemia or from any other condition which affects your body's iron levels.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast feeding. Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking FERODAN.

They will determine if FERODAN is suitable for you.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you get without a

prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking FERODAN.

Some medicines may interfere with FERODAN. These include:

- tetracycline antibiotics (to treat infections), such as tetracycline or doxycycline
- ciprofloxacin, norfloxacin, levofloxacin, moxifloxacin, ofloxacin and chloramphenicol (antibiotics to treat infections)
- bisphosphonates such as alendronate (to prevent loss of bone mass or to treat osteoporosis)
- colestyramine, used to reduce cholesterol and fats in the blood
- antacids (for indigestion)
- preparations containing zinc, calcium, magnesium, phosphorus
- trientine (for Wilson's disease)
- methyldopa (to treat high blood pressure)
- levodopa, levodopa/carbidopa and entacapone (for Parkinson's disease)
- penicillamine (for rheumatoid arthritis)
- levothyroxine (to treat thyroid problems)
- dimercaprol (to treat poisoning with certain metals)
- mycophenolates (to prevent rejection of organ transplants).

These medicines may be affected by FERODAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take FERODAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The recommended daily dose is:

Children 2 to 6 years: Up to 5 mL (for example, 2 mL in the morning, 1 mL at lunchtime and 2 mL at night).

Children 6 to 12 years: 5 to 20 mL (for example, 5 mL three times daily).

Adults and children 12 years and over: 15 to 30 mL (for example, 5-10 mL three times daily).

How to take it

Shake the bottle well and accurately measure the dose with a medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

When to take it

FERODAN should be taken in three divided doses throughout the day.

It is best to take your medicine on an empty stomach, for example, 1 hour before meals or 2 hours after a meal.

Food and certain drinks (including tea, coffee, milk, eggs and whole grains) can reduce the amount of iron absorbed in your stomach.

Do not take antacids (medicines used to treat indigestion) or preparations containing zinc, calcium, magnesium or phosphorus at the same time as FERODAN.

If you need to take one of these preparations take it at least 2 hours before or 2 hours after your dose of FERODAN. These preparations will decrease the absorption of iron.

If you are taking levothyroxine medicine to treat a thyroid problem, do not take it at the

same time as FERODAN.

Take it at least 2 hours before or 2 hours after your dose of FERODAN.

Taking preparations containing vitamin C or eating meat at the same time as you are taking FERODAN may enhance the absorption of iron.

How long to take it

You should not take FERODAN for longer than 6 months, unless your doctor tells you to.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking FERODAN

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FERODAN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not take FERODAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FERODAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the bottle of FERODAN with you if you can.

Initial symptoms of an overdose may include being sick, diarrhoea, a racing heart (tachycardia) and tiredness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FERODAN.

This medicine helps most people with iron deficiency but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick)
- vomiting
- stomach irritation
- constipation
- diarrhoea

- temporary discolouration of the teeth
- stools (bowel motions) becoming dark green or black.

The above list includes the more common side effects of your medicine.

Temporary discolouration of the teeth can be prevented by placing FERODAN on the back of the tongue with a dropper, or by using a straw. Brushing the teeth after taking FERODAN may also minimize the discolouration.

Stools often become dark green or black when you are taking iron preparations. This is caused by unabsorbed iron and is usually harmless. **However, if there is blood in the stools or you have other side effects, such as cramps or stomach pains, contact your doctor as soon as possible.**

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing
- sudden or severe itching, skin rash or hives
- fainting, seizures or fits.

If you experience any of these side effects, you may have a serious allergic reaction to FERODAN. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After taking FERODAN

Storage

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store FERODAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep the bottle tightly closed, and ensure that the child resistant cap is engaged after use.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FERODAN is a syrupy liquid with a fruity odour. The colour of FERODAN may vary from bluish-green to very light yellow to gold.

Ingredients

Each mL of FERODAN contains 30 mg of the active ingredient, ferrous sulfate heptahydrate (which is equivalent to 6 mg of elemental iron).

It also contains:

- Sucrose
- Sorbitol
- Glycerine
- Citric acid
- Lemon flavour
- Pineapple flavour
- Strawberry flavour
- Sodium benzoate
- Sodium bisulphite
- Purified water.

The flavourings used in FERODAN contain:

- Essential oils
- Natural and artificial flavours
- Ethanol
- Polysorbate
- Propylene glycol
- Acetic acid

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

FERODAN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 168 169.

Date of Information

27 May 2020
(Based on datasheet dated 22 May 2020)