PATIENT INFORMATION LEAFLET

FERRITONE

SCHEDULING STATUS: S0

FERRITONE powder

Iron, ascorbic acid (vitamin C), folic acid, cobalamin (vitamin B12)

Contains sweetener (stevia): 5 mg per 5 g sachet

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read this entire leaflet carefully because it contains important information for you.

FERRITONE is available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to use FERRITONE carefully to get the best results from it.

- Keep this leaflet; you may need to read it again.
- Do not share FERRITONE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What FERRITONE is and what it is used for
2. What you need to know before you take/give FERRITONE

MGordon
MC Parma (Pty) Ltd
RA Pharmacist
29/09/2025

3. How to take/give FERRITONE
4. Possible side effects
5. How to store FERRITONE
6. Contents of the pack and other information

1. What FERRITONE is and what it is used for

FERRITONE is a health supplement that provides iron, vitamin C, folic acid, and vitamin B12 (cobalamin). It contributes to the normal formation and proper function of red blood cells and haemoglobin.

2. What you need to know before you take/give FERRITONE

Do not take/give FERRITONE

- If you are or if your child is allergic (hypersensitive) to iron, vitamin C, folic acid, vitamin B12, or any of the other ingredients of FERRITONE (see **What FERRITONE contains**)
- In the presence of iron overload.

Warnings and precautions

FERRITONE provides vitamin B12 that contains cobalamin and cobalt. In case of allergy (hypersensitivity) to cobalt or cobalamin, do not take/give FERRITONE (please see **Do not take/give FERRITONE**).

If any of the following applies to you or your child, please discuss the use of FERRITONE with your doctor, pharmacist, or other healthcare provider before you start taking/giving it:

- You (or your child) produce(s) too little stomach acid as this may interfere with the absorption of the iron in FERRITONE.
- You or your child have/has been diagnosed with hereditary haemorrhagic telangiectasia – an inherited condition that causes abnormal blood vessel formation. People with this condition may have an increased risk of experiencing nosebleeds when using iron supplements such as FERRITONE.
- You have angina or coronary (heart) artery disease and are scheduled to receive a stent. Your doctor may advise you to discontinue FERRITONE prior to the procedure. After the procedure, you should only use it under the supervision of your treating cardiologist.
- You or your child have/has epilepsy or a seizure disorder. While the amount of folic acid in FERRITONE may be too little to impact seizure disorders, you should strictly adhere to the recommended maximum daily dosage (see **How to take/give FERRITONE**).
- You or your child have/has been diagnosed with cancer. Some of the ingredients in FERRITONE may have interactions with anticancer medicines (see **Other medicines and FERRITONE**). You should use FERRITONE only under the supervision of your oncologist.
- You or your child previously had a kidney or urinary stone since supplementation with high doses of vitamin C may increase the risk of developing oxalate urinary stones. You must not exceed the recommended maximum daily dose (see **How to take/give FERRITONE**).
- You or your child have/has been diagnosed with kidney disease as this may further increase the risk of developing kidney stones. You must not exceed the recommended maximum daily dose (see **How to take/give FERRITONE**).

- You or your child have/has been diagnosed with glucose-6-phosphate dehydrogenase deficiency. You must strictly adhere to the recommended maximum daily dose (see **How to take/give FERRITONE**), because taking large doses of vitamin C may damage your/your child's red blood cells.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Other medicines and FERRITONE

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you or your child require(s) antibiotics while taking FERRITONE, please inform the prescribing doctor that you (or your child) are taking a supplement containing iron. If oral antibiotics are prescribed, it should be taken at least 2 hours before, or 4 to 6 hours after, FERRITONE.

Separate the doses of FERRITONE and the following medicines as indicated:

- Bisphosphonates for osteoporosis – separate doses by at least 2 hours.
- Dolutegravir or other integrase inhibitors for HIV (Human Immunodeficiency Virus) infection – dolutegravir should be taken at least 2 hours before or 6 hours after FERRITONE.
- Levodopa/carbidopa for Parkinson's disease – separate doses as much as possible.

- Levothyroxine for an underactive thyroid gland – separate doses by at least 2 hours.
- Methyldopa for high blood pressure – separate doses by at least 2 hours.
- Mycophenolate mofetil to suppress the immune system – FERRITONE should be taken 4 to 6 hours before, or 2 hours after, mycophenolate mofetil.
- Penicillamine to suppress the immune system or for Wilson's disease – separate doses by at least 2 hours.
- Broad-spectrum antibiotics such as Tetracyclines and quinolones – take at least 2 hours before or 6 hours after FERITONE.

Before taking FERRITONE or administering it to your child, please discuss the use of the following medicines with your doctor, pharmacist, or other healthcare provider:

- Aluminium-containing compounds, such as phosphate binders, to manage kidney failure. Patients with kidney failure taking phosphate binders should use FERRITONE only under the supervision of their treating doctor.
- Chemotherapy for cancer. Cancer patients should use FERRITONE only under the supervision of their treating doctor (please see **Warnings and precautions**).
- Contraceptives or hormone replacement therapy, especially if you are known to have low vitamin C levels. FERRITONE may increase blood estrogen levels under these circumstances, and you may experience estrogen-related side effects.
- Medicines for the treatment of epilepsy or seizures as you need to strictly adhere to the recommended daily dose of FERRITONE (see **How to take/give FERRITONE**).

- Pyrimethamine for the treatment of certain parasitic infections or pneumonia, as you may have to temporarily discontinue supplementation with FERRITONE.
- Blood thinners (anticoagulants) such as warfarin as it will be necessary to regularly monitor INR (International Normalised Ratio) levels, but especially when supplementation with FERRITONE is initiated or discontinued.
- Complementary medicines containing acerola and/or rosehip since they usually contain high concentrations of vitamin C, and one must take care not to exceed the tolerable upper intake level of vitamin C.
- Chromium supplements, as FERRITONE may increase chromium absorption. It is best to avoid taking large doses of chromium and FERRITONE together.
- Grape seed supplements, especially if you suffer from high blood pressure, as such supplements in combination with FERRITONE may further increase your blood pressure.

Tell your doctor that you/your child are taking FERRITONE if scheduled to undergo blood, stool, or urine tests. Supplementation with FERRITONE may influence the results of these special investigations.

FERRITONE with food

Calcium, polyphenols, tannins, or other food constituents that are present in the gut may reduce iron absorption when taken at the same time as iron supplements. The iron in FERRITONE has been formulated to prevent such interactions. However, it is still recommended that you take/give FERRITONE on an empty stomach, if possible. People who are unable to tolerate taking FERRITONE on an empty stomach due to

gut-related side effects, should avoid taking it at the same time as dairy, coffee, tea, or cereals (see **How to take/give FERRITONE**).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking FERRITONE.

FERRITONE is considered safe in pregnancy and while breastfeeding when used orally and appropriately. Care must be exercised when FERRITONE is combined with other supplements that contain iron, vitamin C, folic acid, and vitamin B12 to ensure that the upper tolerable intake levels (UL) of these vitamins and minerals are not exceeded.

Driving and using machines

No specific studies have been conducted. Given its side effect profile, it is unlikely that FERRITONE will affect your ability to drive or use machines.

It is not always possible to predict to what extent FERRITONE may interfere with your daily activities. Please ensure that you do not engage in the above activities until you are aware of the measure to which FERRITONE affects you.

3. How to take/give FERRITONE

Do not share your medicines with any other person.

Always take/give FERRITONE exactly as described in this leaflet or as your doctor, pharmacist, or healthcare provider has told you. Check with your doctor, pharmacist, or healthcare provider if you are not sure.

Adults and children 1 year and older

Take/give 1 sachet per day preferably on an empty stomach (see **FERRITONE with food**). Dissolve the contents of the sachet in ± 100 ml of water or juice, and drink immediately. After reconstitution, FERRITONE is a cloudy, slightly sweet suspension with a distinct vanilla taste. Once opened, sachets should be used immediately.

It is necessary to separate the doses of FERRITONE from those of antibiotics, bisphosphonates, and certain other medicines. Some medicines should be taken at least 2 hours before or 4 to 6 hours after FERRITONE (see **Other medicines and FERRITONE**).

You can continue with FERRITONE for as long as you derive benefit from it.

If you take/give more FERRITONE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take/give FERRITONE

If you forget to take/give FERRITONE, take/give the next dose as soon as you remember. Do NOT take/give a double dose to make up for forgotten individual doses.

4. Possible side effects

FERRITONE can have side effects.

Not all side effects reported for FERRITONE are included in this leaflet. Should your/your child's general health worsen or if you/your child experience any untoward effects while taking FERRITONE, please consult your healthcare provider for advice.

It is important not to exceed the recommended dose. FERRITONE is usually well tolerated when used in the prescribed dosage.

Stop taking/giving FERRITONE and immediately report to your doctor or the emergency department of the nearest hospital if you/your child experience any of the following serious side effects:

- Those that occur frequently:
    - Persistent, mild to moderate stomach pain with burning, vomiting, and/or loss of appetite
    - Severe stomach pain or cramps with or without vomiting.
- Those for which the frequency is not known:
    - Skin rash with itching, swelling of the lips, face, tongue or throat, or difficult breathing
    - Severe pain in the flank or lower stomach with blood in the urine and/or difficulty passing urine (with high doses).

If you/your child experience any of the above, it may indicate a serious reaction to FERRITONE and you/your mild may require urgent medical attention.

Stop taking/giving FERRITONE and report to your doctor as soon as possible if you/your child experience any of the following side effects:

- Those that occur less frequently:

- Ulcers in the mouth.

- Those for which the frequency is not known:
  - Any skin rash, including worsening of acne.

Any of the above may indicate a reaction to FERRITONE that may require medical attention.

Please report the following side effects to your doctor if they continue or become bothersome:

- Those that occur frequently:
  - Nausea, vomiting, heartburn, episodic stomach cramps, runny stomach.
- Those that occur less frequently:
  - Dry mouth, episodic stomach pain or irritation, constipation, discolouration/staining of teeth.
- Those for which the frequency is not known:
  - Fatigue, headache, sleeplessness, or sleepiness (in high doses).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of FERRITONE.

In addition, adverse events can also be reported to Flora Force Health Products (Pty) Ltd via email at info@floraforce.co.za or telephonically [0861 336723].

5. How to store FERRITONE

- Store at or below 25 °C in a cool, dry place protected from light and moisture.
- Do not use if the package seal is broken. Do not use damaged or open sachets.
- Do not use after the expiry date stated on the packaging material.
- Do not dispose of unused FERRITONE in drains or sewerage systems (e.g., toilets). Return all unused medicines *to your pharmacist.*
- *STORE ALL MEDICINES OUT OF REACH OF CHILDREN*.

6. Contents of the pack and other information

What FERRITONE contains

Each 5 g sachet contains the following active substances:

Liposomal ferric pyrophosphate	307 mg
Equivalent to ferric pyrophosphate	80 mg
Providing iron (elemental)	24 mg
Magnesium L-ascorbate dihydrate	118 mg
Providing ascorbic acid (vitamin C)	100 mg
and magnesium (elemental)	6.5 mg
L-5-methyltetrahydrofolate	385 µg
Providing folic acid	200 µg
Methylcobalamin	2,5 mg
Providing cobalamin (vitamin B12)	5 µg

Sugar free.

Contains sweetener: 5 mg stevia per sachet.

The inactive ingredients are maize starch, maltodextrin, sunflower lecithin, and vanilla flavour.

What FERRITONE looks like and contents of the pack

An off-white powder with vanilla flavour within a laminated foil sachet packed within an outer carton.

Pack size: 30 sachets

Holder of Certificate of Registration

MC Pharma (Pty) Ltd

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Pretoria

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This leaflet was last revised in

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Registration/Application number

To be allocated by the Authority upon registration.

Access to the corresponding Professional Information

Please visit https://www.floraforce.co.za/