

## Package leaflet: Information for the patient

### Fercelan 202.8 mg/0.8 mg/100 mg hard capsules

ferrous (II) fumarate, folic acid, ascorbic acid (*ferrosi fumaras, acidum folicum, acidum ascorbinicum*)

#### **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 have 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 a doctor if you do not feel better or if you feel worse within 4 weeks.

#### **What is in this leaflet**

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

#### **1. What Fercelan is and what it is used for**

Fercelan contains the active ingredients ferrous fumarate, folic acid and ascorbic acid.

Ferrous fumarate is a form of iron and folic acid is a member of the B group of vitamins. Both iron and folic acid are needed by the body for the formation of red blood cells. If the body does not receive adequate amounts of these nutrients, anaemia (low red blood cell count) can develop.

Fercelan is used for the treatment of iron deficiency states with proven lack of folic acid, in particular one month before conception (or when planning pregnancy) and throughout the third month of gestation.

#### **2. What you need to know before you take Fercelan**

##### **Do not take Fercelan,**

- if you are allergic to ferrous fumarate, folic acid or ascorbic acid or any of the other ingredients of this medicine (listed in section 6).
- if you have too much iron in your body (haemochromatosis, haemosiderosis)
- if you have iron metabolism disorders.
- if you have anaemia that is not caused by iron or folic acid deficiency.
- if you suffer from gastrointestinal disorders.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Fercelan:

- You may have blood test done to determine the cause of your iron deficiency before treatment with this medicine starts.
- While you are taking Fercelan, you may notice a darkening of stools. This is quite commonly seen with iron preparations and you should not worry about this.
- If you have a so called megaloblastic anaemia, you may need blood tests in regular intervals.
- If you have urinary stones, as ascorbic acid may have an effect on stone formation.
- Ascorbic acid interferes with some laboratory tests. Inform your doctor or the laboratory personnel about taking Fercelan.
- If you have severe or terminal renal insufficiency (dialysis) a daily dose of 50 to 100 mg ascorbic acid should not be exceeded due to risk of hyperoxalaemia (too much oxalate in the blood) and crystallisation of oxalate crystals in the kidneys (kidney stones).

#### **Children**

Fercelan is not intended for use in children.

#### **Other medicines and Fercelan**

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

The following medicines can influence Fercelan or can be influenced by Fercelan. Therefore ask your doctor for advice before taking any of them together with Fercelan.

- Acetohydroxamic acid, cefdinir, chloramphenicol, dapsone, quinolones, tetracycline: medicines to treat bacterial infections
- Acetylsalicylic acid, salicylates, non-steroidal anti-inflammatory drugs (NSAR): to treat pain, fever and inflammations
- Anion exchanger, polystyrolsulfonat
- Antacids (aluminium, calcium salts): medicines which neutralise or bind gastric acid
- Cimetidine, omeprazole: medicines, which reduce gastric acid production
- Anticonvulsives (e.g. carbamazepine, phenobarbital, primidone, valproic acid): for the treatment of seizures (fits)
- Antituberculous medicines
- Auranofin: for the treatment of rheumatoid arthritis
- Bisphosphonates: to treat reduced bone density
- Calcium and magnesium preparations, magnesium hydroxide carbonate, magnesium carbonate, sodium hydrogen carbonate
- Entacapone, levodopa: medicines to treat Parkinson's disease
- Folic acid antagonists (e.g. methotrexate, pyrimethamine, triamterene, trimethoprim, sulfonamides)
- Glucarpidase: used during cancer treatment
- Lipoic acid: for the treatment of a disease affecting the nervous system
- Methyl dopa: to treat high blood pressure, especially during pregnancy
- Mycophenolate mofetil: a medicine to suppress the immune system, used to prevent [rejection in organ transplantation](#)
- Pancreatin and analogues: for the treatment of diseases affecting the pancreas
- Penicillamine: for the treatment of rheumatic diseases
- Sulfasalazine: for the treatment of inflammatory bowel diseases
- Tannin protein: certain agents for the treatment of diarrhoea. Tannins are also contained in food such as red wine, black or green tea.
- Thyroid hormones, thyroxine: for the treatment of thyroid diseases
- Tilactase (made from *Aspergillus oryzae*): for the symptomatic treatment of lactose intolerance
- Tiopronin, dimercaprol: to treat poisoning with heavy metals
- Trientine: for the treatment of a genetic disorder in which copper builds up in the body (Wilson's disease)
- Zinc salts

#### **Invented name with food, drink and alcohol**

The capsules should be taken before breakfast or meals.

In case of persisting side effects, Fercelan can be taken with meals.

When Fercelan is administered at the same time as milk and dairy products, caffeine containing drinks (tea, coffee) or alcohol, and food the absorption of Fercelan may be reduced.

#### **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.

Fercelan can be used during pregnancy and breast-feeding.

#### **Driving and using machines**

Fercelan does not affect the ability to drive or operate machines.

#### **Fercelan contains lactose monohydrate (milk sugar)**

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

### **3. How to take Fercelan**

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.

The recommended dose is 1 capsule once a day.

The capsules should be swallowed whole with plenty of liquid before breakfast or meals.

The duration of treatment depends on the severity of iron deficiency.

#### Use in children

Fercelan is not intended for use in children.

#### **If you take more Fercelan than you should**

Overdose can cause iron intoxication.

Symptoms may involve vomiting, gastrointestinal bleeding and diarrhoea, followed by circulatory collapse. If you take too many capsules, or a child takes any capsules, contact a doctor or the nearest hospital immediately.

#### **If you forget to take Fercelan**

Do not take a double dose to make up for a forgotten dose. Just continue with your daily dose.

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.

**Fercelan can cause severe allergic reactions (frequency not known: cannot be estimated from the available data). Tell your doctor straight away if you experience any of the following symptoms:**

- ⊗ difficulty in breathing
- ⊗ rash affecting your body
- ⊗ if you collapse

**Other side effects (frequency not known) include:**

- ⊗ increased blood levels of iron (in case of iron overload)
- ⊗ gastrointestinal problems and stomach pain with nausea and vomiting, diarrhoea, constipation, black coloured faeces and heartburn
- ⊗ severe allergic reaction (anaphylactic reaction)
- ⊗ allergic skin reactions such as itching, hives, redness, swelling and photosensitivity (an abnormally high sensitivity to sunlight)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Fercelan**

Do not store above 30°C.

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 carton. 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.

#### **6. Contents of the pack and other information**

##### **What Fercelan contains**

- The active substances are ferrous (II) fumarate, folic acid and ascorbic acid. Each capsule contains 202.8 mg ferrous (II) fumarate, corresponding to 66.7 mg of elemental iron, 0.8 mg folic acid and 100 mg ascorbic acid.
- The other ingredients are lactose monohydrate, polyacrylate dispersion 30%, colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, stearic acid, erythrosine (E127), red iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and gelatin.

##### **What Fercelan looks like and contents of the pack**

Fercelan are pink, size 0 hard capsules containing 4 reddish-brown mini-tablets, 1 yellow mini-tablet and 3 white mini-tablets. Each capsule is approximately 21.7 mm in length and 7.5 mm in height.

Fercelan is available in blister packs containing 10, 20, 28, 30, 50, 56, 60, 84, 90, 98 and 100 capsules. Not all pack sizes may be marketed.