

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 a doctor if you do not feel better or if vou feel worse.

What is in this leaflet

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

1. What Pregaday is and what it is used for

Package leaflet: Information for the patient Pregaday 322mg/0.35mg Film-coated Tablets Ferrous fumarate and folic acid Pregaday 322mg/0.35mg film-coated Tablets (referred to as Pregaday in this leaflet) contains two active substances Ferrous Fumarate 322.00mg (an iron supplement)

and Folic Acid 0.35mg (a vitamin supplement). These work together in the medicine.

Pregaday belongs to a group of medicines called haematinics (Iron in • if you are allergic to Ferrous combination with Folic Acid).

Pregaday works as a supplement. It provides the body with more iron and folic acid. These are important substances that your body needs to form red blood cells. If you do not have the right amount of these

substances it is possible that you may develop anaemia.

Pregaday is used to prevent and treat low levels of iron and folic acid in the blood during pregnancy after the first thirteen weeks.

During pregnancy the body's demands for iron and folic acid increase. Iron is important for the health of the mother and developing baby. Not enough iron may lead to anaemia in either the mother or baby. It is therefore important that the body gets enough iron for both the mother and the developing baby. Folic acid is very important for the

development of a baby during pregnancy. It is therefore important that the body gets enough folic acid for both the mother and the developing baby.

You must talk to a doctor if you do not feel better or if vou feel worse.

2. What you need to know before vou take Pregadav

Do not take Pregaday:

- Fumarate and Folic Acid or any of the other ingredients of this medicine (listed in section 6)
- if you are less than 13 weeks pregnant
- if you are breast-feeding or trying to become pregnant
- if you have been told you suffer from Vitamin B12 deficiency
- if you suffer from a blood disorder
- if you have had or are having repeated blood transfusions
- if you have a stomach ulcer or other digestive conditions such as regional enteritis or ulcerative colitis
- if you are suffering from anaemia that is not due to a lack of iron

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor before taking Pregaday

- if you have been or you are being treated for a stomach ulcer
- if you have had or you have a folate dependent tumour
- if you have had all or part of your stomach removed

Pregaday contains iron. Keep out of reach and sight of children, as overdose may be fatal.

Children

There is no relevant use of Pregaday in children.

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

Other medicines and Pregaday Tell your doctor if you are taking any other medicines.

- Antibiotics e.g. fluoroquinolones, cotrimoxazole, chloramphenicol, sulphonamides, tetracyclines, neomycin (used for infections)
- Anticonvulsant medicines (used for epilepsy)
- Antacids
- · Penicillamine (used for rheumatoid arthritis)
- Sulfasalazine (used for rheumatoid arthritis and bowel disease, e.g. Crohn's disease)
- Cholestyramine (used for reducing blood cholesterol or control diarrhoea)
- Levodopa or Carbidopa (used for Parkinson's disease)
- Thyroxine (used for thyroid disease)
- Bisphosphonates (used for bone disease)
- Aminopterin and Methotrexate (used for certain cancers)
- Pyrimethamine (used for malaria)
- Trientine (used for Wilson's disease)
- Methyldopa (used for high blood pressure)

• Zinc

• Any other medicine, including medicines obtained without a prescription

Pregaday with food and drink If you drink tea, coffee or milk or eat eggs at the same time as taking Pregaday your body may absorb less of the iron supplement, which may reduce the effect of this medicine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, ask your doctor for advice before taking this medicine.

Only use if you are more than 13 weeks pregnant. Do not use if you are breast-feeding or trying to become pregnant.

Driving and using machines.

There are no known effects on driving or using machines.

3. How to take Pregaday

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.

IMPORTANT: Your doctor or pharmacist will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

DO NOT EXCEED THE STATED DOSE.



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Too much iron can be harmful. Swallow the tablet whole with a glass of water.

The recommended dose for adults

- The usual dose is one tablet each day
- The tablets come in a pack with the days of the week marked on the back. This will help you to remember to take your medicine. Make sure you press out the tablet for the correct day of the week.

If you take more Pregaday than you should

If you accidentally take too much, contact the nearest hospital casualty department or your doctor immediately.

Symptoms of an overdose include stomach pain, diarrhoea or being sick, within an hour of taking too much. Heart problems or collapse may follow.

If you forget to take Pregaday

If you miss a tablet take one when you remember. Never take two tablets on the same day.

If you miss several tablets take a single tablet and talk to your doctor.

If you stop taking Pregaday

Keep taking this medicine for as long as your doctor or pharmacist tells you to. Do not stop taking this medicine just because you feel better.

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.

Seek immediate medical help if you have an allergic reaction.

This includes any of the following symptoms:

- Difficulties in breathing
- Swelling of your eyelids, face or lips
- Rash or itching

Not known: frequency cannot be estimated from the available data

- Upset stomach
- Anorexia (e.g. loss of appetite)
- Sickness
- Constipation
- Diarrhoea
- Darkening of stools

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 via the Yellow Card Scheme website: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregaday

Keep this medicine out of the sight and reach of children. An overdose can be fatal.

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

Store below 25°C. Keep the blister in the outer carton in order to protect from light.

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 Pregaday contains

- The active substances are Ferrous Fumarate and Folic Acid. Each tablet contains 322mg ferrous fumarate (equivalent to 100mg iron) and 0.35 mg folic acid.
- The other ingredients are maize starch, sodium lauryl sulphate, gelatin and liquid paraffin. The ingredients in the tablet coat are hydroxypropylmethyl cellulose (E464), hydroxypropyl cellulose (E463), red iron oxide (E172), titanium dioxide (E171), and either propylene glycol, or acetylated monoglycerides.

What Pregaday looks like and contents of the pack

Pregaday film-coated tablets are round and brownish pink with 'PREGADAY' written on one side. Pregaday comes in cartons containing 28 tablets (2 calendar blister packs of 14).

Marketing Authorisation Holder RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.

Manufacturer

Haupt Pharma Wuelfing GmbH, Bethelner Landstrasse 18, Gronau/Leine, 31028, Germany.

This leaflet was last revised in 05/2020.

Other sources of information

If this leaflet is difficult to see or read or you would like it in a different format, please contact

RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.



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