

Package leaflet: Information for the user
Refolinon® 15 mg tablets
Leucovorin calcium

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 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Refolinon is and what it is used for

Refolinon contains the active substance leucovorin calcium which is chemically related to a vitamin called folic acid. Refolinon increases the levels of folic acid in your body. Methotrexate (a medicine used to treat cancer) can lower your body's levels of folic acid. Refolinon is used to reverse this and help to maintain folic acid levels. This is known as 'leucovorin rescue'.

Refolinon is also used to treat a form of anaemia (megaloblastic) which results from low levels of folic acid.

You should ask your doctor if you are unsure why you have been given Refolinon.

2. What you need to know before you take Refolinon

Do not take Refolinon if:

- you are allergic (hypersensitive) to leucovorin calcium or any of the other ingredients of this medicine (listed in section 6).
- you have pernicious anaemia or other megaloblastic anaemia where vitamin B12 is deficient.

Other medicines and Refolinon

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can affect the way Refolinon works, or Refolinon itself can reduce the effectiveness of other medicines taken at the same time.

- The effectiveness of Refolinon can be reduced by **chloramphenicol** (an antibiotic).
- Refolinon can reduce the effectiveness of drugs used to treat **epilepsy** (phenobarbital, phenytoin or primidone) and lead to more frequent seizures (fits).
- Refolinon may increase the side effects of **fluorouracil** (used to treat cancer).

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before you take this medicine.

Breast-feeding

If you are breast-feeding, speak to your doctor who will advise whether you should use an alternative method of feeding your baby.

Driving and using machines

Refolinon is not expected to affect your ability to drive or use machines.

Refolinon contains lactose

Refolinon contains lactose, a type of 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 Refolinon

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

The usual dose in adults and children is as follows:

The tablets should be swallowed with a glass of water. It is important to take your medicine at the right times.

Refolinon for leucovorin rescue: 15mg (1 tablet) every 6 hours for 48 hours. Refolinon for leucovorin rescue therapy is usually started 24 hours after the start of methotrexate treatment.

Refolinon for megaloblastic anaemia: 15mg (1 tablet) daily until your doctor tells you to stop.

If you take more Refolinon than you should

If you accidentally take too much Refolinon contact your doctor. Side-effects with Refolinon are rare, since it is similar to a naturally occurring vitamin.

If you forget to take Refolinon

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

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

If you stop taking Refolinon

Do not stop taking Refolinon unless your doctor tells you to. If you suddenly stop taking this medicine your condition may return.

If you have any further questions on how to take 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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

If Refolinon is given with another drug called fluorouracil (to treat cancer) the following side effects have been reported:

- decreased white blood cell count or low platelets in the blood. Symptoms may include bruising, nose bleeds or rash. Your doctor will take regular blood tests to check these.
- sore and inflamed mouth (stomatitis) and/or diarrhoea.

If you have received Refolinon by injection, prior to receiving the tablets, you can also get a high temperature.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Refolinon

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

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

Store below 25 °C. Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What Refolinon contains

The active substance in Refolinon tablets is leucovorin (folinic acid) as the calcium salt. Each tablet contains 15mg of leucovorin.

The other ingredients are: microcrystalline cellulose, magnesium stearate and lactose (see section 2 Refolinon contains lactose).

What Refolinon looks like and contents of the pack

Refolinon tablets are light yellow and are scored and marked CF on one side

The tablets are supplied in plastic containers of 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited

Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom

Manufacturer:
Orion Corporation
Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

Orion Corporation
Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

This leaflet was last revised in 05/2020

Ref: RE 8_0