

LEFRAVA FILM COATED TABLETS

Leflunomide (10mg, 20mg)

What is in this leaflet

1. What Lefrava is used for
2. How Lefrava works
3. Before you use Lefrava
4. How to use Lefrava
5. While you are using it
6. Side effects
7. Storage and Disposal of Lefrava
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Lefrava is used for

Lefrava is used to treat adult with:

- Active rheumatoid arthritis to improve physical function of the body
- Arthritis symptoms include inflammation of joints, swelling, difficulty in moving and pain. Other symptoms that affect the entire body include loss of appetite, fever, loss of energy and anaemia (lack of red blood cells).
- Active psoriatic arthritis
- Symptoms include patches of red, scaly skin (skin lesions).

How Lefrava works

Lefrava belongs to a group of medicines called anti-rheumatic medicines. It contains the active substance leflunomide. It works by reducing pain, inflammation, swelling and stiffness over a period of weeks or months by slowing down the disease and its effects on the joints.

Before you use Lefrava

- When you must not use it

Do not take Lefrava if:

- You are allergic (hypersensitive) to leflunomide (especially a serious skin reaction, often accompanied by fever, joint pain, red skin stains, or blisters e.g. Stevens-Johnson syndrome) or to any of the other ingredients of this medicine (listed in Ingredients below).
- You have any liver problems
- You have moderate to severe kidney problems
- You have severely low numbers of proteins in your blood (hypoproteinaemia)

- You suffer from any problem which affects your immune system (such as AIDS)
- You have any problems with your bone marrow, or if you have low numbers of red or white cells in your blood or a reduced number of platelets
- You are suffering from a serious infection
- You are pregnant, think you may be pregnant, or are breast-feeding.
- You are not using reliable birth control.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lefrava.

- Before you start to use it

Check with your doctor before taking Lefrava if:

- You have ever suffered from tuberculosis or interstitial lung disease.
- You have problems related to your blood and bone marrow.
- You are taking other rheumatoid arthritis medicines (see 'Taking other medicines')
- You are having psoriasis and diabetes
- You are taking medicine that affect your immune system such as methotrexate.
- You have rare genetic problems such as galactose or lactose intolerance and glucose-galactose malabsorption.
- You are male and wish to father a child. Men should contact their doctor who may advise them to stop taking Lefrava and take certain medicines to remove Lefrava rapidly from their body. If both blood concentration measured are low, you should then wait for at least another 3 months before attempting to father a child.

Lefrava can occasionally cause some problems with your blood, liver, lungs, or nerves in your arms or legs. It may also cause some serious allergic reactions, or increase the

chance of severe infection. (see 'side effects')

Your doctor will carry out blood tests at regular intervals, before and during treatment with Lefrava, to monitor your blood cells and liver. Your doctor will also check your blood pressure regularly as Lefrava can cause an increase in blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Lefrava.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as these combinations are inadvisable:

- Antimalarials (e.g. chloroquine and hydroxychloroquine)
- Intramuscular or oral gold,
- D-penicillamine
- Benzylpenicillin, Ciprofloxacin, rifampicin (antibiotic)
- Zidovudine (anti-virus)
- Azathioprine, methotrexate and other medicines that affect your immune system
- Activated charcoal.
- Warfarin (used to prevent blood clots)
- Caffeine
- Indomethacin and ketoprofen (use as painkiller or anti-inflammatory)
- Furosemide (reduce water retention in the body)
- Cimetidine (reduce stomach acid production)
- Theophylline (for asthma treatment)
- Simvastatin, atorvastatin, pravastatin, rosuvastatin and cholestyramine (cholesterol lowering agent).

If you are already taking a nonsteroidal anti-inflammatory drug (NSAID) and/or corticosteroids, you may continue to take them after starting Lefrava.

Vaccinations

If you have to be vaccinated, ask your doctor for advice. Certain vaccinations such as live attenuated vaccines should not be given while taking Lefrava, and for a certain amount of time after stopping treatment.

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How to use Lefrava

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

- Swallow your tablets orally in whole with plenty of water.
- You can take this medicine with or without food.

- How much to use

The usual starting dosage for Lefrava is one 100mg leflunomide once daily for the first three days. After this, most people need a dose of:

- For rheumatoid arthritis: 10mg or 20mg Lefrava once daily, depending on the severity of the disease.
- For psoriatic arthritis: 20mg Lefrava once daily.

Lefrava is not recommended for use in children and adolescents below 18 years of age.

- When to use it

Take Lefrava at about the same time each day unless your doctor tells you otherwise.

- How long to use it

It may take about 4 weeks or longer until you start to feel an improvement in your condition. Some people may even still feel further improvement after 4 to 6 months of therapy. You will normally take Lefrava over long periods of time.

- If you forget to use it

If you forget to take your tablet, take as soon as you remember. If it is nearing the time for next dose, leave out that dose completely and take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

While you are using it

- Things you must do

Tell your doctor immediately if:

- You are pregnant or think you may be pregnant while taking Lefrava, as the risk of having a baby with serious birth effects increased. Women of childbearing potential must not take Lefrava without using reliable contraceptive measures.

Tell your doctor if you plan to become pregnant after stopping Lefrava as this may take up to 2 years. This may be reduced to a few weeks by taking certain medicines (colestyramine or activated charcoal) which speed up removal of Lefrava from your body.

In either case it should be confirmed by a blood test that Lefrava has been sufficiently removed from your body and you should then wait for at least another month before you become pregnant.

- You are breast-feeding as leflunomide passes into the breast milk.

Tell your doctor if you develop skin ulcer during treatment with Lefrava.

- Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Lefrava, or change the dosage, without checking with your doctor.

- Things to be careful of Driving and using machines

Lefrava can make you feel dizzy which may impair your ability to concentrate and react. If you are affected, do not drive, or do not use machines.

Consult doctor if you want to discontinue Lefrava and switch to another medicine regarding about the washout procedure.

Side Effect

Like all medicines, Lefrava can cause side effects, although not everyone gets them.

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

Tell your doctor immediately.

Common side effects:

- A decrease in the number of white blood cells
- Mild allergic reactions
- Loss of appetite, weight loss (usually insignificant)
- Tiredness
- Headache, dizziness
- Abnormal skin sensations like tingling
- Problems in the nerves of the arms or legs (peripheral neuropathy)
- Mild increase in blood pressure
- Diarrhoea
- Nausea, vomiting
- Inflammation of the mouth or mouth ulcers
- Abdominal pain
- An increase in some liver test results
- Increased hair loss
- Eczema, dry skin rash, itching
- Inflammation in the sheath that surrounds the tendons
- An increase of certain enzymes in the blood (creatinine)

Uncommon side effects:

- A decrease in the number of red blood cells and blood platelets.
- A decrease in the levels of potassium or phosphate in the blood
- Anxiety
- Taste disturbances
- Nettle rash
- Tendon rupture
- An increase in the levels of fat in the blood (cholesterol and triglycerides)

Rare side effects:

- An increase in the numbers of blood cells called eosinophiles (eosinophilia); decrease in the number of white blood cells or all blood cells.
- Severe increase in blood pressure
- Inflammation of the lung (interstitial lung disease)
- An increase in some liver results which may develop into serious conditions such as inflammation and yellowing of eyes and skin.
- Severe infections which may be fatal

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- An increase of certain enzymes in the blood (lactate dehydrogenase).

Very rare side effects:

- A marked decrease of some white blood cells
- Severe and potentially severe allergic reactions
- Inflammation of blood vessels
- Inflammation of the pancreas
- Severe liver injury such as liver failure or cell death which may be fatal
- Severe sometimes life-threatening skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).

Other side effects such as kidney failure, a decrease in the levels of uric acid in your blood, pulmonary hypertension, male infertility (which is reversible once treatment with this medicine is stopped), cutaneous lupus (characterized by rash/erythema on skin areas that are exposed to light), psoriasis (new or worsening), and DRESS and Skin ulcer (Round, open sore in the skin through which the underlying tissues can be seen), may also occur with an unknown frequency.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lefrava

Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C. Keep the container tightly closed.
- Do not take this medicine after the expiry date, which is stated on the pack.

Disposal

If you have any unwanted tablets do not put them in wastewater or household rubbish. Ask your pharmacist how to dispose of tablets

you do not need.
This will help to protect the environment.

Product Description

What it looks like

Lefrava 10mg Film Coated Tablets– White to off-white, round film coated tablets debossed with ‘L’ on one side and ‘10’ on other side.

Lefrava 20mg Film Coated Tablets– Yellow to light yellow, triangular film coated tablets debossed with ‘L’ on one side and ‘20’ on other side.

Ingredients

- Active ingredients
The active substance of Lefrava 10mg Film Coated Tablets is 10 mg Leflunomide.

The active substance of Lefrava 20 mg Film Coated Tablets is 20 mg Leflunomide.

- Inactive ingredients
Tablet core:
 - Lactose Monohydrate
 - Corn Starch
 - Crospovidone
 - Povidone
 - Magnesium Stearate

Film coat:

Lefrava 10mg Film Coated Tablets: Opadry Complete Film Coating System 03F58763 White

Lefrava 20mg Film Coated Tablets: Opadry Complete Film Coating System 03F52274 Yellow

MAL number(s):

Lefrava 10mg Film Coated Tablets: MALXXXXXXXXX

Lefrava 20mg Film Coated Tablet: MALXXXXXXXXX

Manufacturer

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Product Registration Holder

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