

Lunava[®] tablets

leflunomide

Consumer Medicine Information

Please read this leaflet carefully before you start Lunava.

What is in this leaflet

This leaflet answers some common questions about Lunava.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lunava against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Lunava is used for

Lunava is a type of medicine used to treat rheumatoid arthritis. Lunava helps to slow down the process of joint damage and to relieve the symptoms of the disease, such as joint tenderness and swelling, pain and morning stiffness.

Lunava works by selectively interfering with the ability of white blood cells called lymphocytes to produce the disease response that ultimately leads to pain, inflammation and joint damage.

Your doctor, however, may have prescribed Lunava for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take Lunava if you:

- have any diseases which reduce your body's natural defences such as bacterial or viral infections
- have any diseases of the blood
- have any serious skin disorders
- have liver disease
- have a condition called hypoproteinaemia (when you do not have enough protein in your blood)
- are pregnant or plan to become pregnant
- are not using reliable birth control
- are breastfeeding

You must not become pregnant while taking Lunava and for a certain period of time after stopping Lunava.

Lunava may increase the risk of birth defects.

Women of childbearing potential must use reliable contraception while taking Lunava.

Do not take it if you are breastfeeding or planning to breastfeed.

Lunava passes into breast milk and therefore there is a possibility that the breast fed baby may be affected.

Do not take Lunava if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Lunava to a child or adolescent.

Lunava is not approved for use in children or adolescents under 18 years old.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor immediately if you think you could be pregnant while taking Lunava.

Tell your doctor if you intend to become pregnant or father a child. Lunava may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Lunava and may need to undergo a wash-out procedure. Your doctor will discuss the wash-out procedure with you.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- a decrease in the number of white blood cells
- liver problems
- kidney problems
- chronic infections

- an illness which lowered your body's resistance to disease
- tuberculosis
- lung problems, such as interstitial lung disease (an inflammation of lung tissue) which is a serious and potentially fatal disease

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take Lunava.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Lunava. These include:

- warfarin, a medicine used to stop blood clots
- some medicines used for diabetes
- some medicines used to treat epilepsy
- some medicines used for tuberculosis (TB)
- some medicines used to lower cholesterol

These medicines may be affected by Lunava, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

In certain situations, for example, if you experience a serious side effect, you change your medication or you want to fall pregnant, your doctor will ask you to take medication that will help your body get rid of Lunava faster.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Lunava.

How to take it

How much to take

Your doctor will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The standard dose for this medicine is one 100mg tablet per day for the first 3 days, and after that one 10mg or 20mg tablet daily.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

These directions may differ from the information contained in this leaflet. If you take the wrong dose, Lunava may not work as well.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

It does not matter if you take Lunava before or after food.

Take Lunava at about the same time each day.

Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

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

This may increase the chance of you getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Lunava.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Lunava.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Lunava.

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Tell your doctor before stopping contraception. You must continue

using appropriate reliable contraception (the 'Pill' or condoms) while you are taking Lunava.

If you have an infection or notice a fever or signs of an infection while taking this medicine, tell your doctor immediately.

If your skin becomes itchy or yellow, if the whites of your eyes become yellow, or if you start to bleed or bruise easily, stop taking it and tell your doctor or pharmacist immediately.

You may be developing a liver problem. Your doctor may need to take blood samples to monitor the health of your liver and blood cells while you are taking Lunava.

Tell your doctor immediately if you develop new or worsening symptoms such as a cough or trouble breathing.

Inflammation of the lung tissue which can be fatal, has been reported in some patients.

Tell your doctor if you develop symptoms such as pins and needles or tingling in the hands or feet or numbness or weakness of the arms and legs.

Tell your doctor if you need to have a vaccination during treatment with this medicine or for 6 months after stopping treatment.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

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 Lunava, or lower the dosage, without checking with your doctor.

Things to be careful of

The effects of alcohol could be made worse while taking Lunava. It is recommended that you minimise

your alcohol intake while taking Lunava.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lunava.
It helps most people with arthritis, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea
- rashes, itchy skin
- hair loss
- weight loss
- unusual tiredness or weakness
- nausea and vomiting
- abdominal pain

These are the more common side effects of Lunava Tablets.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs and symptoms of severe infection eg Fever
- severe upper stomach pain, often with nausea and vomiting
- severe skin rash or sores in your mouth
- your skin becomes pale, you start to feel tired, you become prone to infections or bruising
- if you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever
- if you develop blisters and bleeding in the lips, eyes, mouth, nose and genitals.

These may be serious side effects of Lunava. You may need urgent medical attention. Serious side effects are uncommon.

Lunava decreases your body's immune response and can cause some of the side effects listed above.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes (jaundice)
- thickened patches of red skin

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Lunava. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.
Other side effects not listed above may occur in some consumers.

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

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

Storage

Keep your tablets in the container until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking Lunava Tablets or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Manufacturer

Lunava is supplied in Australia by:

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

Registration Number

AUST R 164966 – Lunava 10mg
AUST R 164967 – Lunava 20mg
AUST R 164968 – Lunava 100mg*

Date of Information:

January 2015

*Not available in Australia

® Registered Trade Mark

Product description

What the tablets look like

Tablets, film coated

10 mg: white, round biconvex tablets
30's (bottle);

20 mg: yellow, round biconvex tablets
with a scoreline on one side 30's
(bottle);

100 mg*: white, oblong biconvex
tablets with a scoreline on one side 3's
(blister).

Ingredients

Active Leflunomide.

Inactive

- microcrystalline cellulose
- lactose
- maize starch
- povidone
- crospovidone
- colloidal anhydrous silica
- magnesium stearate
- Opadry II complete film coating system OY-LS-28908 white (10mg and 100mg tablets)
- Opadry II aqueous film coating OY-SR-6497 Yellow (20mg tablets)