Arava®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Arava?

Arava contains the active ingredient leflunomide. Arava is used to treat rheumatoid or psoriatic arthritis. For more information, see Section 1. Why am I using Arava? in the full CMI.

2. What should I know before I use Arava?

Do not use if you have ever had an allergic reaction to leflunomide, teriflunomide or any of the ingredients listed at the end of the CMI. Do not use if you are pregnant or plan to become pregnant, are not using reliable birth control, or are breastfeeding.

There are a number of other circumstances in which a person must not use this medicine. Check if these apply to you before taking Arava (see the full CMI for more details).

Talk to your doctor if you have any other medical conditions or take any other medicines. For more information, see Section 2. What should I know before I use Arava? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Arava and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Arava?

- The standard dose for this medicine is 100 mg per day for the first 3 days, and after that one 10 mg or 20 mg tablet daily.
- Swallow the tablets whole with a full glass of water, at about the same time each day. You can take it with or without food.

More instructions can be found in Section 4. How do I use Arava? in the full CMI.

5. What should I know while using Arava?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Arava. • **Call your doctor straight away if**: you become pregnant while you are taking this medicine; you have an infection/notice a fever or signs of an infection; your skin becomes itchy or yellow / the whites of your eyes become yellow / if you start to bleed or bruise easily; you develop new /worsening cough or trouble breathing. • Tell your doctor before stopping contraception.
Things you should not do	• Do not take more than the recommended dose unless your doctor tells you to. • Do not stop taking Arava, or lower the dosage, without checking with your doctor.
Drinking alcohol	• Tell your doctor if you drink alcohol. • It is recommended that you minimise your alcohol intake while taking Arava.
Looking after your medicine	• Store it in a cool dry place below 25°C away from moisture, heat or sunlight

For more information, see Section 5. What should I know while using Arava? in the full CMI.

6. Are there any side effects?

Common side effects include: diarrhoea; nausea and vomiting; abdominal pain; weight loss; rashes, itchy skin; hair loss; unusual tiredness or weakness. Serious side effects include: fever; severe upper stomach pain; severe skin rash or sores in your mouth; pale skin, fatigue or increased infections and bruising; cough or trouble breathing; blisters and bleeding in the lips, eyes, mouth, nose and genitals; skin ulcer. Very serious side effects include: allergic reaction symptoms.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Arava®

Active ingredient: *leflunomide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Arava. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Arava.**

Where to find information in this leaflet:

1. Why am I using Arava?
2. What should I know before I use Arava?
3. What if I am taking other medicines?
4. How do I use Arava?
5. What should I know while using Arava?
6. Are there any side effects?
7. Product details

1. Why am I using Arava?

Arava contains the active ingredient leflunomide. Arava is an immunosuppressive medicine, which means that it works by reducing the activity of the immune system.

Arava is used to treat rheumatoid or psoriatic arthritis.

Arava 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.

Arava 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.

2. What should I know before I use Arava?

Warnings

Do not use Arava if you:

- are allergic to leflunomide, teriflunomide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- have any diseases which reduce your body's natural defenses 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
- are male wishing to father children

Check with your doctor if you:

- have or have had any other medical conditions, especially:
  - 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
- take any medicines for any other condition
- are allergic to any other substances such as foods, preservatives or dyes
- plan to have surgery

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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

- Tell your doctor immediately if you think you could be pregnant while taking Arava.
- Tell your doctor if you intend to become pregnant or father a child.

Arava may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Arava and may need to undergo a wash-out procedure. Your doctor will discuss the wash-out procedure with you.

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

Men wishing to father a child should discontinue use of Arava and undergo a washout procedure or wait 2 years after treatment cessation.

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

- Tell your doctor if you are breast feeding or planning to breastfeed.

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

Use in Children

Do not give Arava to a child or adolescent.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Arava and affect how it works.

- 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Arava.

4. How do I use Arava?

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 100 mg per day for the first 3 days, and after that one 10 mg or 20 mg tablet daily.
- Follow the instructions provided and use Arava until your doctor tells you to stop. The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

When to take Arava

- Arava should be taken 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.
- It does not matter if you take Arava before or after food.

How to take Arava

- Swallow the tablets whole with a full glass of water.

If you forget to use Arava

Arava should be used regularly at the same time each day. If you miss your dose at the usual time—and there is still a long time to go before your next dose—take it as soon as you remember. Then go back to taking it as you would normally.

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

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

If you use too much Arava

If you think that you have used too much Arava, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Arava?

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 Arava faster.

Things you should do

- Tell your doctor before stopping contraception. You must continue using appropriate reliable contraception (the 'Pill' or condoms) while you are taking Arava.
- 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.
- Tell your doctor if you develop skin ulcer (open sore) during treatment with Arava see Section 6. Are there any side effects?
- Tell your doctor if you will have or have had recent major surgery, or if you still have an unhealed wound following surgery. Arava may impair wound healing.
- Tell your doctor if you experience unexplained muscle pain, tenderness (soreness when the muscle is pressed) or muscle weakness with or without fever while you are taking Arava.
- Tell your doctor if you develop severe inflammatory reactions. Symptoms such as a prolonged high fever, extreme tiredness, or swollen glands. If you experience these symptoms, contact your doctor immediately. Early treatment is important and can help you get better.

Call your doctor straight away if:

- you become pregnant while you are taking this medicine. Stop taking it and tell your doctor or pharmacist immediately.
- you have an infection or notice a fever or signs of an infection
- 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 Arava.
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using Arava.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not stop taking Arava, or lower the dosage, without checking with your doctor.
- 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place—below 25°C—away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep your tablets in the container until it is time to take them. If you take the tablets out of the box or the bottle they may not keep well.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gut-related: • diarrhoea • nausea and vomiting • abdominal pain • weight loss **Skin-related:** • paresthesia (numbness, tingling of the skin) • rashes, itchy skin	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Other: • hair loss • unusual tiredness or weakness • dizziness • headache • anorexia	

Serious side effects

Serious side effects	What to do
Skin-related: • severe skin rash or sores in your mouth • blisters and bleeding in the lips, eyes, mouth, nose and genitals. • pale skin, prone to infection or bruising and feeling tired • skin ulcer (a round, open sore in the skin through which the underlying tissues can be seen) **Other:** • signs and symptoms of severe infection (e.g. fever) • severe upper stomach pain, often with nausea and vomiting • new or worsening symptoms such as cough or trouble breathing, with or without a fever. • pulmonary nodule (small, abnormal spots or masses in the lungs with unknown frequency)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
Allergic reaction-related: • 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	**Stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Arava contains

Active ingredient (main ingredient)	leflunomide
Other ingredients (inactive ingredients)	lactose monohydrate maize starch povidone colloidal anhydrous silica magnesium stearate crospovidone hypromellose macrogol 8000 purified talc titanium dioxide iron oxide yellow (20 mg tablet only)
Potential allergens	Contains lactose

Do not take this medicine if you are allergic to any of these ingredients.

Arava does not contain sucrose, gluten, tartrazine or any other azo dyes.

What Arava looks like

Arava 10 mg tablets are white to almost white, round film-coated tablets with the embossing ZBN. Arava 10 mg tablets are supplied in bottles in packs of 10# and 30 tablets. AUST R 69692

Arava 20 mg tablets are yellowish to ochre, spherical triangular film-coated tablets with the embossing ZBO. Arava 20 mg tablets are supplied in bottles in packs of 10# and 30 tablets. AUST R 69694.

#Presentations currently not marketed.

Who distributes Arava

Distributed in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:
Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
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