

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 ALIMTA?

ALIMTA contains the active ingredient pemetrexed disodium heptahydrate. ALIMTA is used to treat different types of lung cancer.

For more information, see Section [1. Why am I using ALIMTA?](#) in the full CMI.

2. What should I know before I use ALIMTA?

Do not use if you have ever had an allergic reaction to pemetrexed disodium heptahydrate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ALIMTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALIMTA 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 ALIMTA?

- Your doctor will decide the dosage of ALIMTA that you are given. This will depend on your condition, if you have experienced any side effects, and other factors, such as your weight
- ALIMTA is given as an infusion (drip) into your veins over a 10-minute period by your doctor or nurse.

More instructions can be found in Section [4. How do I use ALIMTA?](#) in the full CMI.

5. What should I know while using ALIMTA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ALIMTA. • Tell your doctor immediately if you become pregnant while receiving this medicine. • Take all medicines or vitamins prescribed by your doctor as 'premedication'. These may help to minimise side effects. • Keep all your doctor's appointments so that your progress can be checked.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ALIMTA affects you. • ALIMTA may cause tiredness or drowsiness in some people.
Looking after your medicine	• ALIMTA will be stored in the hospital pharmacy or on the ward.

For more information, see Section [5. What should I know while using ALIMTA?](#) In the full CMI.

6. Are there any side effects?

Common side effects may include fatigue, nausea, vomiting, diarrhoea, mouth ulcers, being more prone to infections and bruising. Serious side effects may include inflammation of the large intestines, severe skin/allergic reactions, chest infection, kidney impairment or liver impairment.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALIMTA. **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 ALIMTA.**

Where to find information in this leaflet:

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

1. Why am I using ALIMTA?

ALIMTA contains the active ingredient pemetrexed disodium heptahydrate.

ALIMTA belongs to a group of medicines called cytotoxic or antineoplastic agents. They may also be called chemotherapy medicines.

It affects enzymes within cancer cells to kill cancer cells or prevent them growing and multiplying.

ALIMTA is used to treat:

- **mesothelioma**, a rare cancer of the lungs often related to exposure to asbestos.
- **non-small cell lung cancer**, a type of lung cancer.

2. What should I know before I use ALIMTA?

Warnings

Do not use ALIMTA if:

- you are **allergic** to any medicine containing **pemetrexed disodium heptahydrate**, or **any of the ingredients listed at the end of this leaflet**. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have kidney problems. Depending on the severity of your condition, your doctor may choose not to treat you with ALIMTA.
- have high blood pressure or diabetes as these conditions may increase your risk of developing kidney problems while being treated with ALIMTA.
- have heart problems or other cardiovascular risk factors (such as high cholesterol levels, are a smoker) as these may increase your risk of experiencing a heart attack or stroke while being treated with ALIMTA.

- have had radiation therapy (radiotherapy) as this may increase your risk of developing a lung condition called 'radiation pneumonitis' or a skin condition called 'radiation recall' while being treated with ALIMTA.
- have a build-up of fluid between your lungs and chest (called 'pleural effusion') or in your abdomen (belly) (called 'ascites'). Your doctor may choose to drain the excess liquid before starting treatment with ALIMTA.
- are taking non-steroidal anti-inflammatory drugs (e.g. aspirin, ibuprofen). Your doctor may choose to delay treatment with ALIMTA.

Tell your doctor if you are scheduled for any vaccinations or have recently been vaccinated. Some vaccines (live vaccines) should not be given while you are being treated with ALIMTA. Check with your doctor before receiving any vaccines.

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

Tell your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Pregnancy and breastfeeding should be avoided during treatment with ALIMTA. Your doctor can discuss with you the risks and benefits involved.

Children 18 years of age and under

ALIMTA is not recommended for use in children under the age of 18 years.

The safety and effectiveness in children younger than 18 years have not been established.

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 ALIMTA and affect how it works.

Medicines that may increase the effect of ALIMTA include:

- medicines used to treat arthritis or pain from inflammation such as ibuprofen or other non-steroidal anti-inflammatory medicines (NSAIDs).
- medicines used to treat heartburn and acid regurgitation such as omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole (proton pump inhibitors).

- medicines used to treat infections such as penicillin.
- medicines used to treat gout or gouty arthritis such as probenecid.

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

4. How do I use ALIMTA?

How much to use

Your doctor will decide the dosage of ALIMTA that you are given. This will depend on your condition, if you have experienced any side effects, and other factors, such as your weight and height.

When to use ALIMTA

ALIMTA is given once every three weeks (one treatment cycle). Your doctor will advise how many treatment cycles you need.

Before each infusion you will have samples of your blood taken to check that you have enough blood cells to receive ALIMTA. Your doctor may decide to change your dose or delay treating you depending on your general condition and if your blood cell counts are too low.

How ALIMTA will be given

ALIMTA is given as an infusion (drip) into your veins over a 10-minute period.

Never inject ALIMTA yourself.

Your doctor or nurse will inject ALIMTA for you.

When treating certain cancers, you may also be given other chemotherapy medicines.

If you use too much ALIMTA

As ALIMTA is given to you under the supervision of your doctor, it is unlikely that you will use too much.

However, if you suspect that you have been given too much you may:

- phone the Poisons Information Centre (by calling 13 11 26), 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 ALIMTA?

Premedication

Your doctor should advise you to take certain medicines or vitamin while taking ALIMTA. These may help to minimise side effects.

Your doctor should advise you to take a folate supplement or a multivitamin containing folate once daily for at least five days in the week before your first ALIMTA dose. This

should be continued throughout your treatment cycles and for at least three weeks following completion of ALIMTA treatment.

Your doctor should advise you to have a vitamin B₁₂ injection during the week before your first dose of ALIMTA. Additional vitamin B₁₂ injections should be given once every three treatment cycles.

Your doctor may advise you to take an oral corticosteroid such as dexamethasone to reduce the likelihood and severity of skin rashes.

Your doctor may advise you to take a medicine to help reduce nausea (antiemetic).

Your doctor may also advise you to receive an infusion (drip) of fluid into your veins for hydration.

Things you should do

- **If you become pregnant while receiving this medicine, tell your doctor immediately.**
- Remind any doctor, dentist or pharmacist you visit that you are using ALIMTA.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using ALIMTA. It may affect other medicines used during surgery.
- If you are about to have any blood tests, tell your doctor that you are using ALIMTA.
- **Keep all your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- Take your daily folate supplement until your doctor tells you to stop.
- Check with your doctor that your vitamin B₁₂ injections are up to date.
- Remain well hydrated by drinking plenty of fluids while using ALIMTA. This will reduce your risk of developing kidney problems.
- Check with your doctor before receiving any vaccinations. Live vaccines are not recommended while you are using ALIMTA.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALIMTA affects you.

ALIMTA may cause tiredness or drowsiness in some people.

Looking after your medicine

ALIMTA will be stored in the hospital pharmacy or on the ward.

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
General: - tiredness, sleepiness (fatigue) - fever - feeling thirsty/dehydrated - hair loss - change in taste - build-up of fluid in lower legs and ankles - abdominal, chest, back or leg pain. Stomach related: - heartburn (typically a burning sensation that begins just below the breastbone and moves up towards the throat) - indigestion (dyspepsia) – discomfort in the upper stomach - pain in the stomach, upset stomach - nausea, vomiting - loss of appetite - diarrhoea, constipation. Skin related: - rash, itchy, or peeling skin - hives. Eye related: - red, watery, itchy, or swollen eyes or eyelids with or without discharge - Blurred vision, sensitivity to light. Mouth related: - pain, redness, swelling, pus or sores in your mouth - sore throat - difficulty swallowing.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Blood-cell related: Symptoms of abnormal blood cell counts may include: - tiredness, weakness, feeling faint or dizzy - breathlessness - looking pale - fever, chills, swollen lymph nodes, or other signs of infection - ulcers in the mouth, or sore mouth or throat	Tell your doctor as soon as possible if you notice any of these side effects.

Serious side effects	What to do
- bleeding or bruising more easily than normal - prolonged bleeding - bleeding from your gums or nose, or blood in urine or stools. Liver related: Symptoms of liver impairment may include: - yellowing of the skin or eyes - swelling or pain in your abdomen (belly), swelling in your ankles and legs - dark-coloured urine or light-coloured stool - loss of appetite - frequent itchiness. Kidney related: Symptoms of kidney impairment may include: - decreased urination (little to none) or dark urine - pain when urinating - build-up of fluid in your legs, ankles, and feet. Nervous system related: - numbness, prickling, or tingling in your hands/arms or feet/legs - sharp, jabbing, or burning pain - extreme sensitivity to touch, or loss of sensation - lack of coordination, muscle weakness.	
Stomach related: Inflammation of the large intestines. Symptoms may include: - diarrhoea with blood or mucus - constant urge to have a bowel movement - bloating - stomach pain - fever. Chest related: - difficulty breathing, shortness of breath that gets worse when active or lying down - a feeling of suffocation or drowning that worsens when lying down - dry cough, coughing up frothy or bloody mucus - chest pain - slow, fast, or irregular heartbeat.	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.

Serious side effects	What to do
Skin related: - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Steven-Johnsons syndrome) - severe skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge (Erythema multiforme) - severe skin rash, with redness, and peeling skin which may appear like a sunburn (Radiation recall). Allergy related: - sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, eyes, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.	

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

Some side effects (for example changes in liver enzymes, changes in kidney function, and blood cell levels) can only be found when your doctor does tests from time to time to check your progress.

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. 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

ALIMTA is only available with a doctor's prescription.

What ALIMTA contains

Active ingredient (main ingredient)	pemetrexed disodium heptahydrate
Other ingredients (inactive ingredients)	hydrochloric acid mannitol sodium hydroxide

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

What ALIMTA looks like

ALIMTA is a white to light yellow or green-yellow powder and is available in a glass vial container with a rubber stopper.

ALIMTA is supplied in 100 mg and 500 mg vials.

ALIMTA 100 mg, AUST R 146828.

ALIMTA 500 mg, AUST R 96731

Who distributes ALIMTA

ALIMTA is supplied by:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

SYDNEY NSW 2000

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