ALIMTA®

pemetrexed disodium heptahydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALIMTA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about ALIMTA and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ALIMTA against the benefits this medicine is expected to have for you.

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

Keep this leaflet.
You may need to read it again.

What ALIMTA is used for

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.

It 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.

Your doctor may have prescribed it for another reason.

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

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

ALIMTA may be used in combination with other chemotherapy drugs.

Before you are given ALIMTA

When you must not be given it

Do not take ALIMTA if you have an allergy to:

- any medicine containing pemetrexed disodium heptahydrate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

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

- kidney problems

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Pregnancy and breast-feeding should be avoided during ALIMTA treatment. Your doctor can discuss with you the risks and benefits involved.

This medicine is not recommended for use in children under the age of 18 years.
Safety and effectiveness in children younger than 18 years have not been established.

If you have not told your doctor about any of the above, tell him/her before you take ALIMTA.

Taking 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 therapy cycles and for at least three weeks following completion of ALIMTA treatment.

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

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

Ask your doctor if you have any questions about why these other medicines have been prescribed for you.

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 maybe affected by ALIMTA or may affect how it works. These include:

- medicines used to treat arthritis or pain from inflammation such as ibuprofen or other non-steroidal anti-inflammatory medicines (NSAIDs).

You may need different amounts of your medicines or to stop taking them for a few days or you may need to take different medicines.

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

How ALIMTA will be given

Follow all directions given to you by your doctor or pharmacist carefully.

How much is given

Your doctor will decide the dosage of ALIMTA you should take. This will depend on your condition and other factors, such as your weight.

How it is given

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

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

Your doctor or nurse will inject ALIMTA for you.

Never inject ALIMTA yourself. Always let your doctor or nurse do this.

How often it is given

ALIMTA is given once every three weeks (1 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.

Overdose

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

However, if you experience any side effects after being given ALIMTA, immediately tell your doctor or nurse or go to the Emergency Department at your nearest hospital.
You may need urgent medical attention.

While you are taking ALIMTA

Things you must do

Always take your daily folate supplement until your doctor tells you to stop.

Always check with your doctor that your vitamin B12 injections are up to date.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving ALIMTA.

Tell any other doctors, dentists and pharmacists who treat you that you are receiving this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are receiving this medicine.
It may affect other medicines used during surgery.

If you become pregnant while receiving this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are receiving this medicine.

Keep all of 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.

Things to be careful of

Be careful driving or operating machinery until you know how ALIMTA affects you.
This medicine may cause tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALIMTA.
This medicine is to help people with mesothelioma or non-small cell lung cancer, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- fatigue, drowsiness, fainting
- feeling dehydrated
- pain in the stomach, upset stomach, nausea, loss of appetite, vomiting
- diarrhoea, constipation, dark urine
- muscle weakness
- skin irritation, burning or prickling sensation
- hair loss
- conjunctivitis (red and itchy eyes with or without discharge and crusty eyelids)
- coughing, difficulty breathing, wheezing caused by inflammation of the lung
- abdominal, chest, back or leg pain.

Additional side effects when used in combination with other chemotherapy agents include:

- taste change
- loss of feeling
- kidney problems where you pass little or no urine.

The above lists include the more common side effects of your medicine. When used in combination with other chemotherapy medicine, also refer to the other product's consumer medicine information leaflet for a list of other possible side effects.

Tell your doctor as soon as possible if you notice any of the following:

- fever or infection with a temperature, sweating or other signs of infection
- pain, redness, swelling or sores in your mouth
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips or tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- tiredness, feeling faint or breathless, if you look pale
- bleeding or bruising more easily than normal.

The above list includes serious side effects which may require medical attention.

In rare cases ALIMTA can cause inflammation of the colon (large bowel). Tell your doctor as soon as possible if you experience any of the following symptoms:

- diarrhoea with blood and mucus
- stomach pain
- fever.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- chest pain or fast heart beat
- bleeding from the gums, nose or mouth, any bleeding that will not stop, reddish or pinkish urine, unexpected bruising.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, abnormal blood tests showing low cell counts) can only be found when your doctor does tests to check your progress.

After having ALIMTA

Storage

This medicine will be stored in the hospital pharmacy or on the ward.

It will be kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

ALIMTA is a white to off white powder and is available in a glass vial container with a rubber stopper.

Ingredients

ALIMTA is supplied in 500 mg and 100 mg vials.

The 500 mg vial of ALIMTA contains pemetrexed disodium heptahydrate equivalent to 500 mg pemetrexed and 500 mg of mannitol.

The 100 mg vial of ALIMTA contains pemetrexed disodium heptahydrate equivalent to 100 mg pemetrexed and 106.4 mg of mannitol.

Hydrochloric acid and/or sodium hydroxide may be added to both presentations to adjust pH.

Supplier

ALIMTA is supplied by
Eli Lilly Australia Pty Ltd
Level 9, 60 Margaret Street
Sydney NSW 2000

Australian Registration Number:

ALIMTA 500 mg, AUST R 96731

ALIMTA 100 mg, AUST R 146828

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