

## PART III: CONSUMER INFORMATION

Pr **ALIMTA**<sup>®</sup>  
(pemetrexed disodium for injection)

This leaflet is part III of a three-part "Product Monograph" published when ALIMTA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALIMTA. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

ALIMTA is used in the treatment of the following types of cancers:

- Malignant pleural mesothelioma (cancer of the lining of the chest cavity) in combination with cisplatin (another anti-cancer drug).
- Nonsquamous locally advanced or metastatic non-small cell lung cancer as:
  - Initial treatment in combination with cisplatin.
  - Maintenance treatment given alone immediately after four cycles of platinum-based first-line chemotherapy.
  - Second line treatment given alone after prior chemotherapy.

#### **What it does:**

ALIMTA is an antifolate anticancer agent that works by disrupting the metabolic processes that are essential for cell replication. It helps to stop the cancer cells from multiplying.

#### **When it should not be used:**

Do not take ALIMTA if you:

- are allergic to pemetrexed disodium or any of the ingredients in ALIMTA.
- have received or are going to receive the Yellow Fever vaccine.

#### **What the medicinal ingredient is:**

ALIMTA contains the active ingredient called pemetrexed disodium.

#### **What the important nonmedicinal ingredients are:**

ALIMTA contains mannitol. Hydrochloric acid and/or sodium hydroxide, may have been added to adjust pH.

#### **What dosage forms it comes in:**

ALIMTA is supplied as sterile freeze-dried powder for intravenous infusion and is available in single-dose vials. Each vial contains either 100 mg or 500 mg pemetrexed as pemetrexed disodium.

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions**

- ALIMTA should be administered under the supervision of a qualified physician experienced in the use of anticancer agents.
- Liver toxicity and rare cases of fatal liver failure have been reported in clinical trial patients treated with ALIMTA alone or in combination with other anticancer drugs.

**To lower your chances of side effects of ALIMTA, you must also take folic acid and vitamin B<sub>12</sub> injections prior to and during your treatment with ALIMTA.**

BEFORE you receive ALIMTA talk to your doctor or pharmacist if:

- you have a severe hypersensitivity reaction to ALIMTA or to any other ingredient used in the formulation.
- you are pregnant or planning to get pregnant (ALIMTA may cause harm to an unborn child).
- you plan to father a child. (ALIMTA may cause irreversible infertility).
- you are breast feeding.
- you are under 18 years old.
- you have a kidney disease.
- you have a liver disease.
- you have a heart problem.
- you have ever had radiation therapy.
- you have recently received or are planning on receiving a vaccine against Yellow Fever or any live vaccines.

You should discuss effective birth control methods with your doctor. Male patients should not father a child during the treatment and up to 6 months after stopping the treatment.

### INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have taken other medications, including prescription and nonprescription medicines, vitamins, and natural health products.

Drugs that may interact with ALIMTA include:

- NSAIDs (nonsteroidal anti-inflammatory drugs, e.g. ibuprofen): you should stop taking them for at least 5 days before, the day of, and at least 2 days after ALIMTA treatment. If it is necessary to take NSAIDs inform your doctor and you will be monitored accordingly.

### PROPER USE OF THIS MEDICATION

#### **Usual dose:**

ALIMTA is slowly infused (injected) into a vein. The injection or infusion will last about 10 minutes. You will usually receive ALIMTA once every 21 days (3 weeks).

You may receive ALIMTA alone or in combination with cisplatin, another anti-cancer agent. Your doctor will determine your treatment plan, be sure to ask your doctor or health care team if

you have any questions.

If your doctor has prescribed cisplatin, it will be infused in your vein for about 2 hours starting about 30 minutes after your treatment with ALIMTA.

#### Pre-Medications

**To lower your chances of experiencing harmful side effects, it is important for you to take the following medication and vitamins prior to and/or during your treatment with ALIMTA.**

#### *Corticosteroid*

Your doctor will prescribe a medicine called a “corticosteroid” to take the day before, the day of, and the day after ALIMTA treatment. Corticosteroid medicines lower your chances for getting skin reactions with ALIMTA.

#### *Folic Acid Tablets*

You must start taking 350- 600 micrograms of folic acid every day for at least 5 days out of the 7 days before your first dose of ALIMTA. You must keep taking folic acid every day during the time you are getting treatment with ALIMTA and for 21 days after your last treatment.

You can get folic acid vitamins over-the-counter. Folic acid is also found in many multivitamin pills. Ask your doctor or pharmacist for help if you are not sure how to choose a folic acid product.

#### *Vitamin B<sub>12</sub> Injection*

Your doctor will give you vitamin B<sub>12</sub> injections while you are getting treatment with ALIMTA. You will get your first vitamin B<sub>12</sub> injection during the week before your first dose of ALIMTA, and then about every 9 weeks during treatment until 3 weeks after the last dose of ALIMTA.

Contact your doctor if you forget to take your pre-medications.

You will have regular blood tests before and during your treatment with ALIMTA. Your doctor may adjust your dose of ALIMTA or delay treatment based on the results of your blood tests and on your general condition.

#### **Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **Missed Dose:**

Contact your physician immediately for further instructions.

### **SIDE-EFFECTS AND WHAT TO DO ABOUT THEM**

Most patients taking ALIMTA will have side effects. Sometimes it is not possible to tell whether ALIMTA, another medicine, or the cancer itself is causing these side effects. **Call your doctor**

**right away if you have a fever, chills, diarrhea, or mouth sores.** These symptoms could mean you have an infection.

The most common side effects of ALIMTA when taken alone or with cisplatin are:

- Stomach upset, including nausea, vomiting, diarrhea, and constipation.
- Low blood cell counts
  - Low red blood cells may make you feel tired, get tired easily, appear pale, and become short of breath.
  - Low white blood cells may give you a greater chance for infection. If you have a fever (temperature above 38°C) or other signs of infection, call your doctor right away.
  - Low platelets give you a greater chance for bleeding. Your doctor will do blood tests to check your blood counts before and during treatment with ALIMTA.
- Tiredness. You may feel tired or weak for a few days after your ALIMTA treatments. If you have severe weakness or tiredness, call your doctor.
- Mouth, throat, or lip sores (stomatitis, pharyngitis). You may get redness or sores in your mouth, throat, or on your lips. These symptoms may happen a few days after ALIMTA treatment. Talk with your doctor about proper mouth and throat care.
- Loss of appetite. You may lose your appetite and lose weight during your treatment.
- Kidney. Your kidney function may be decreased, sometimes seriously, which may make you feel unwell. Your doctor may do blood tests to monitor your kidney function.
- Rash. You may get a rash or itching during treatment. These usually appear between treatments with ALIMTA and usually go away before the next treatment. Sometimes you may get severe skin reactions. Call your doctor if you get a severe rash or itching.
- Fever.

Effects on heart and brain have been reported uncommonly in clinical studies. Severe effects on stomach and intestine including bleeding has been uncommonly reported in clinical studies. Sometimes the effect on intestine are worse after radiation. In clinical studies, severe effects on lung and breathing have been reported. Blood flow disturbance leading to tissue damage has been reported.

Rare cases of unusual swelling in the legs or the face (edema) have been reported.

A small number of patients have reported changes in mood/ depression.

Be sure to tell your doctor if your breathing gets worse while you are on ALIMTA.

Talk with your doctor, nurse, or pharmacist about any side effect that bothers you or that doesn't go away. It is important that you continue to take your folic acid and vitamin B<sub>12</sub> supplements even if you experience serious side effects.

## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist*
		Only if severe	In all cases	
Common	Allergic reaction		✓	
	Bleeding		✓	
	Breathing (Any change)		✓	
	Chest pain (new or worsening)		✓	
	Diarrhea		✓	
	Fever	✓		
	Mouth, throat or lip sores		✓	
	Nausea	✓		
	Skin rash	✓		
	Swallowing difficulty		✓	
	Tiredness	✓		
	Vomiting	✓		

\*Continue taking your folic acid and vitamin B<sub>12</sub> injections even if you have serious side effects. Common=1% to <10%

***This is not a complete list of side effects. For any unexpected effects while taking ALIMTA, contact your doctor or pharmacist.***

## HOW TO STORE IT

ALIMTA powder should be stored at controlled room temperature 20-25°C, excursions permitted to 15-30°C. Reconstituted and infusion solutions can be stored at refrigerated conditions (2-8°C) for up to 24 hours.

## REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701D  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

**NOTE:** Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

## MORE INFORMATION

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972 or visit the website at [www.lilly.ca](http://www.lilly.ca).

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

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