NL069FSQR01

FPO

PATIENT INFORMATION
ALIMTA™ (uh-LIM-tuh)
(pemetrexed for injection)
for Intravenous Use

What is ALIMTA?
ALIMTA is a prescription medicine used to treat:
- **a kind of lung cancer called non-squamous non-small cell lung cancer (NSCLC).** ALIMTA is used:
  - as the first treatment in combination with pembrolizumab and platinum chemotherapy when your lung cancer with no abnormal EGFR or ALK gene has spread (advanced NSCLC).
  - as the first treatment in combination with cisplatin when your lung cancer has spread (advanced NSCLC).
  - alone as maintenance treatment after you have received 4 cycles of chemotherapy that contains platinum for first treatment of your advanced NSCLC and your cancer has not progressed.
  - alone when your lung cancer has returned or spread after prior chemotherapy.

  ALIMTA is not for use for the treatment of people with squamous cell non-small cell lung cancer.
- **a kind of cancer called malignant pleural mesothelioma.** This cancer affects the lining of the lungs and chest wall. ALIMTA is used in combination with cisplatin as the first treatment for malignant pleural mesothelioma that cannot be removed by surgery or you are not able to have surgery.

ALIMTA has not been shown to be safe and effective in children.

Do not take ALIMTA if you have had a severe allergic reaction to any medicine that contains pemetrexed.

Before taking ALIMTA, tell your healthcare provider about all of your medical conditions, including if you:
- have kidney problems.
- have had radiation therapy.
- are pregnant or plan to become pregnant**.** ALIMTA can harm your unborn baby.

  Females who are able to become pregnant:
  Your healthcare provider will check to see if you are pregnant before you start treatment with ALIMTA.
  You should use effective birth control (contraception) during treatment with ALIMTA and for 6 months after the last dose. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with ALIMTA.
  Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with ALIMTA and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed**.** It is not known if ALIMTA passes into breast milk. Do not breastfeed during treatment with ALIMTA and for 1 week after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Tell your healthcare provider if you have kidney problems and take a medicine that contains ibuprofen. You should avoid taking ibuprofen for 2 days before, the day of, and 2 days after receiving treatment with ALIMTA.

How is ALIMTA given?
- **It is very important to take folic acid and vitamin B_{12} during your treatment with ALIMTA to lower your risk of harmful side effects.**
  - Take folic acid exactly as prescribed by your healthcare provider 1 time a day, beginning 7 days (1 week) before your first dose of ALIMTA and continue taking folic acid until 21 days (3 weeks) after your last dose of ALIMTA.
  - Your healthcare provider will give you vitamin B_{12} injections during treatment with ALIMTA. You will get your first vitamin B_{12} injection 7 days (1 week) before your first dose of ALIMTA, and then every 3 cycles.
- Your healthcare provider will prescribe a medicine called corticosteroid for you to take 2 times a day for 3 days, beginning the day before each treatment with ALIMTA.
- ALIMTA is given to you by intravenous (IV) infusion into your vein. The infusion is given over 10 minutes.
- ALIMTA is usually given once every 21 days (3 weeks).

What are the possible side effects of ALIMTA?
ALIMTA can cause serious side effects, including:
- **Low blood cell counts.** Low blood cell counts can be severe, including low white blood cell counts (neutropenia), low platelet counts (thrombocytopenia), and low red blood cell counts (anemia). Your healthcare provider will do blood tests to check your blood cell counts regularly during your treatment with ALIMTA. **Tell your healthcare provider right away if you have any signs of infection, fever, bleeding, or severe tiredness during your treatment with ALIMTA.**
- **Kidney problems, including kidney failure.** ALIMTA can cause severe kidney problems that can lead to death. Severe vomiting or diarrhea can lead to loss of fluids (dehydration) which may cause kidney problems to become worse. Tell your healthcare provider right away if you have a decrease in amount of urine.
- **Severe skin reactions.** Severe skin reactions that may lead to death can happen with ALIMTA. Tell your healthcare provider right away if you develop blisters, skin sores, skin peeling, or painful sores, or ulcers in your mouth, nose, throat or genital area.
- **Lung problems (pneumonitis).** ALIMTA can cause serious lung problems that can lead to death. Tell your healthcare provider right away if you get any new or worsening symptoms of shortness of breath, cough, or fever.
- **Radiation recall.** Radiation recall is a skin reaction that can happen in people who have received radiation treatment in the past and are treated with ALIMTA. Tell your healthcare provider if you get swelling, blistering, or a rash that looks like a sunburn in an area that was previously treated with radiation.

The most common side effects of ALIMTA when given alone are:
- tiredness
- nausea
- loss of appetite

The most common side effects of ALIMTA when given with cisplatin are:
- vomiting
- swelling or sores in your mouth or sore throat
- constipation
- low white blood cell counts (neutropenia)
- low platelet counts (thrombocytopenia)
- low red blood cell counts (anemia)

The most common side effects of ALIMTA when given with pembrolizumab and platinum chemotherapy are:
- tiredness and weakness
- constipation
- loss of appetite
- vomiting
- shortness of breath
- nausea
- diarrhea
- rash
- cough
- fever

ALIMTA may cause fertility problems in males. This may affect your ability to father a child. It is not known if these effects are reversible. Talk to your healthcare provider if this is a concern for you.
Your healthcare provider will do blood tests to check for side effects during treatment with ALIMTA. Your healthcare provider may change your dose of ALIMTA, delay treatment, or stop treatment if you have certain side effects.
Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
These are not all the side effects of ALIMTA. For more information, ask your healthcare provider or pharmacist.
Call your doctor for medical advice about side effects.

How should I store ALIMTA?
- Store below 30 °C [86°F]

Handling of Prepared Dosage Solution
- This product is preservative free and therefore the prepared dosing solution should be used immediately.
- If not used immediately, store the dosing solution under refrigeration for up to 24 hours at 2°C to 8°C [36°F to 46°F].
- Discard unused contents of the vials.

Keep ALIMTA and all medicines out of the sight and the reach of children.

General information about the safe and effective use of ALIMTA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.
Do not use this medicine after the expiry date which is stated on the immediate label and carton after 'EXP'. The expiry date refers to the last day of that month.
You can ask your pharmacist or healthcare provider for information about ALIMTA that is written for health professionals.

What are the ingredients in ALIMTA?
Active ingredient: pemetrexed
Inactive ingredients: mannitol, nitrogen, water for injection, hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

How Supplied
ALIMTA, pemetrexed for injection, is a sterile white to either light yellowish or green yellowish lyophilized powder supplied in single-dose vials for reconstitution for intravenous infusion.

Carton containing one (1) single-dose vial of 100 mg pemetrexed.
Carton containing one (1) single-dose vial of 500 mg pemetrexed.
Not all strengths, pack sizes or presentations may be registered or marketed.

Marketing authorization holder for Jordan:
Eli Lilly Export S.A., Geneva, Switzerland

Marketing authorization holder for Kuwait and UAE:
Eli Lilly Nederland B.V.,
Papendorpseweg 83, 3528 BJ Utrecht,
The Netherlands

Marketing authorization holder for Lebanon:
Lilly France, 2 rue Colonel Lilly, 67640, Fegersheim, France

Manufactured by:
Vianex S.A. Plant C,
16th km Marathonos Avenue,
Pallini Attiki, 15351, Greece

Packaged and released by:
Lilly France, Zone industrielle,
2 rue du Colonel Lilly,
Fegersheim, 67640, France

THIS IS A MEDICAMENT
- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab health ministers
Union of Arab Pharmacists

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