

PATIENT INFORMATION
Pemetrexed (pem-e-TREX-ed) Injection
for intravenous use

What is Pemetrexed Injection?

Pemetrexed Injection is a prescription medicine used to treat:

- **a kind of lung cancer called non-squamous non-small cell lung cancer (NSCLC).** Pemetrexed Injection 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.

Pemetrexed Injection 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. Pemetrexed Injection 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.

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

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

Before taking Pemetrexed Injection, 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. Pemetrexed Injection 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 Pemetrexed Injection.
You should use effective birth control (contraception) during treatment with Pemetrexed Injection 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 Pemetrexed Injection.
Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with Pemetrexed Injection and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if Pemetrexed Injection passes into breast milk. Do not breastfeed during treatment with Pemetrexed Injection 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 Pemetrexed Injection.

How is Pemetrexed Injection given?

- **It is very important to take folic acid and vitamin B12 during your treatment with Pemetrexed Injection 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 Pemetrexed Injection and continue taking folic acid until 21 days (3 weeks) after your last dose of Pemetrexed Injection.

- Your healthcare provider will give you vitamin B12 injections during treatment with Pemetrexed Injection. You will get your first vitamin B12 injection 7 days (1 week) before your first dose of Pemetrexed Injection, 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 Pemetrexed Injection.
- Pemetrexed Injection is given to you by intravenous (IV) infusion into your vein. The infusion is given over 10 minutes.
- Pemetrexed Injection is usually given once every 21 days (3 weeks).

What are the possible side effects of Pemetrexed Injection?

Pemetrexed Injection 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 Pemetrexed Injection. **Tell your healthcare provider right away if you have any signs of infection, fever, bleeding, or severe tiredness during your treatment with Pemetrexed Injection.**
- **Kidney problems, including kidney failure.** Pemetrexed Injection 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 Pemetrexed Injection. 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).** Pemetrexed Injection 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 Pemetrexed Injection. 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 Pemetrexed Injection when given alone are:

- tiredness
- nausea
- loss of appetite

The most common side effects of Pemetrexed Injection 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 Pemetrexed Injection when given with pembrolizumab and platinum chemotherapy are:

- tiredness and weakness
- constipation
- loss of appetite
- vomiting
- shortness of breath
- nausea
- diarrhea
- rash
- cough
- fever

Pemetrexed Injection 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 Pemetrexed Injection. Your healthcare provider may change your dose of Pemetrexed Injection, 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 Pemetrexed Injection. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Pemetrexed Injection.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about Pemetrexed Injection that is written for health professionals.

What are the ingredients in Pemetrexed Injection?

Active ingredient: pemetrexed

Inactive ingredients: citric acid anhydrous, L-methionine, monothioglycerol and Water for injection.

Hydrochloric acid and sodium hydroxide may have been added to adjust pH.

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For more information call 1-866-941-7875.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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