

PATIENT INFORMATION

PEMETREXED FOR INJECTION, USP

(pem" e trex' ed)

What is pemetrexed for injection?

Pemetrexed for injection is a prescription medicine used to treat:

- **a kind of lung cancer called non-squamous non-small cell lung cancer (NSCLC).** Pemetrexed for 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.
- **a kind of cancer called malignant pleural mesothelioma.** This cancer affects the lining of the lungs and chest wall. Pemetrexed for 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.

It is not known if pemetrexed for injection is safe and effective in children.

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

Before taking pemetrexed for 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 for injection can harm your unborn baby.
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with pemetrexed for injection and for 6 months after the final dose. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with pemetrexed for injection.
 - **Males** with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with pemetrexed for injection and for 3 months after the final dose.
- are breastfeeding or plan to breastfeed. It is not known if pemetrexed passes into breast milk. Do not breastfeed during treatment with pemetrexed for injection and for 1 week after the final 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 for injection.

How is pemetrexed for injection given?

- **It is very important to take folic acid and vitamin B₁₂ during your treatment with pemetrexed for 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 for injection and continue taking folic acid until 21 days (3 weeks) after your last dose of pemetrexed for injection.
 - Your healthcare provider will give you vitamin B₁₂ injections during treatment with pemetrexed for injection. You will get your first vitamin B₁₂ injection 7 days (1 week) before your first dose of pemetrexed for 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 for injection.
- Pemetrexed for injection is given to you by intravenous (IV) infusion into your vein. The infusion is given over 10 minutes.
- Pemetrexed for injection is usually given once every 21 days (3 weeks).

What are the possible side effects of pemetrexed for injection?

Pemetrexed for 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 a blood test to check your blood cell counts regularly during your treatment with pemetrexed for injection. **Tell your healthcare provider right away if you have any signs of infection, fever, bleeding, or severe tiredness during your treatment with pemetrexed for injection.**
- **Kidney problems, including kidney failure.** Pemetrexed for 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 for 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 for 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 for 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 for injection when given alone are:

- tiredness
- nausea
- loss of appetite

The most common side effects of pemetrexed for 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 for injection when given with pembrolizumab and platinum chemotherapy are:

- tiredness/weakness
- constipation
- loss of appetite
- vomiting
- nausea
- diarrhea
- rash
- cough

- shortness of breath
- fever

Pemetrexed for 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 test to check for side effects during treatment with pemetrexed for injection. Your healthcare provider may change your dose of pemetrexed for 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 for 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 for 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 for injection that is written for health professionals.

What are the ingredients in pemetrexed for injection?

Active ingredient: pemetrexed

Inactive ingredients: mannitol, hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

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

**Pemetrexed for Injection, USP
1000 mg/vial**

Manufactured by:

Gland Pharma Limited

India

ML No. 03/VP/AP/2011/F/R

Manufactured for:

Apotex Corp.

Weston, Florida

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