

Pemetrexed APOTEX Powder for Injection

Contains the active ingredient pemetrexed (as disodium)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about pemetrexed. 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 listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Pemetrexed APOTEX Powder for Injection, which is given as an intravenous infusion. It contains the active ingredient pemetrexed, as the disodium salt.

It 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.

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

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

How it works

Pemetrexed 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.

Pemetrexed may be used in combination with other chemotherapy drugs.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you are given this medicine

When you must not be given it

Do not take this medicine if you are hypersensitive to, or have had an allergic reaction to pemetrexed or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

Before you are given it

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:
 - kidney problems.
3. You are currently pregnant or you plan to become pregnant. This medicine should not be given during pregnancy. You and your doctor should discuss the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. This medicine should not be given whilst breastfeeding. You and your doctor should discuss the risks and benefits involved.
5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with pemetrexed. These include:

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

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with pemetrexed.

Taking pre-medication

Your doctor should advise you to take certain medicines or vitamin while taking pemetrexed. 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 pemetrexed dose. This should be continued throughout your therapy cycles and for at least three weeks following completion of pemetrexed treatment.

Your doctor should also advise you to have a vitamin B12 injection during the week before your first dose of pemetrexed. 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.

How this medicine will be given

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much will be given

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

How it is given

Pemetrexed 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 pemetrexed for you.

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

How often it is given

Pemetrexed 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 pemetrexed. 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.

If you are given too much (overdose)

As pemetrexed 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 pemetrexed, immediately tell your doctor or nurse or telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

While you are being treated with this medicine

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 being treated with pemetrexed.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with 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 when driving or operating machinery until you know how this medicine 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are being treated with pemetrexed or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- fatigue, drowsiness, fainting
- feeling dehydrated
- pain in the stomach, upset stomach, nausea, loss of appetite, vomiting
- diarrhoea, constipation
- 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
- swelling
- 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. These may be serious side effects and you may need medical attention:

- 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.

In rare cases pemetrexed 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 you experience any of the following, contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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.

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

Other side effects not listed above may occur in some patients.

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.

Storage and disposal

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 will stay below 25°C.

Product description

What Pemetrexed APOTEX Powder for Injection looks like

100 mg and 500 mg strengths: white to either light yellow or green-yellow powder.

Pack of 1 vial.

Ingredients

Each vial contains 100 mg or 500 mg of pemetrexed as the active ingredient.

Each vial also contains the following inactive ingredients:

- mannitol.
- hydrochloric acid and/or sodium hydroxide may have been added to both strengths to adjust pH.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

*Australian Registration
Numbers*

Pemetrexed APOTEX 100 mg
Powder (vial): AUST R 210429.

Pemetrexed APOTEX 500 mg
Powder (vial): AUST R 210440.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered
trade marks of Apotex Inc.

This leaflet was last updated in May
2017.