

# PEMETREXED EVER PHARMA

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using PEMETREXED EVER PHARMA?

PEMETREXED EVER PHARMA contains the active ingredient pemetrexed disodium hemipentahydrate. PEMETREXED EVER PHARMA is used to **treat** mesothelioma, a rare cancer of the lungs often related to exposure to asbestos and non-small cell lung cancer, a type of lung cancer.

For more information, see Section [1. Why am I using PEMETREXED EVER PHARMA?](#) in the full CMI.

### 2. What should I know before I use PEMETREXED EVER PHARMA?

Do not use if you have ever had an allergic reaction to PEMETREXED EVER PHARMA or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use PEMETREXED EVER PHARMA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PEMETREXED EVER PHARMA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use PEMETREXED EVER PHARMA?

Pemetrexed is given as an infusion(drip) into your veins over a 10 minute period. Pemetrexed is given once every three weeks (1 treatment cycle). Your doctor will advise how many treatment cycles you need.

More instructions can be found in Section [4. How do I use PEMETREXED EVER PHARMA?](#) in the full CMI.

### 5. What should I know while using PEMETREXED EVER PHARMA?

<b>Things you should do</b>	Remind any doctor, dentist or pharmacist you visit that you are using PEMETREXED EVER PHARMA. 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 Keep all of your doctor's appointments so that your progress can be checked.
<b>Things you should not do</b>	Do not stop receiving PEMETREXED EVER PHARMA because you are feeling better, unless advised by your doctor
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how PEMETREXED EVER PHARMA 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.
<b>Looking after your medicine</b>	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 stays below 25 °C.

For more information, see Section [5. What should I know while using PEMETREXED EVER PHARMA?](#) in the full CMI.

### 6. Are there any side effects?

Some common side effects include fatigue, drowsiness, feeling dehydrated, pain in stomach, diarrhoea, muscle weakness, hair loss. Some serious side effects that need to be noted include fever, pain redness swelling or sores in your mouth, sudden signs of allergy such as rash, itching, swelling of the face, lips or tongue, bleeding or bruising more than usual- If you notice these you should advise your doctor immediately. This is not a list of all side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# PEMETREXED EVER PHARMA

Active ingredient: *pemetrexed disodium hemipentahydrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PEMETREXED EVER PHARMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PEMETREXED EVER PHARMA.**

**Where to find information in this leaflet:**

- [1. Why am I using PEMETREXED EVER PHARMA?](#)
- [2. What should I know before I use PEMETREXED EVER PHARMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PEMETREXED EVER PHARMA?](#)
- [5. What should I know while using PEMETREXED EVER PHARMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using PEMETREXED EVER PHARMA?

PEMETREXED EVER PHARMA contains the active ingredient **pemetrexed disodium hemipentahydrate**. PEMETREXED EVER PHARMA 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 EVER PHARMA 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.

## 2. WHAT SHOULD I KNOW BEFORE I USE PEMETREXED EVER PHARMA?

### Warnings

**Do not use PEMETREXED EVER PHARMA if:**

- you are allergic to pemetrexed disodium hemipentahydrate, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you are not sure whether you should be given this medicine, talk to your doctor.

**Tell your doctor if you have or have had any of the following medical conditions**

- Kidney problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Pregnancy and breast-feeding should be avoided during Pemetrexed treatment. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**This medicine is not recommended for use in children under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established

### Taking Premedication

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

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

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with PEMETREXED EVER PHARMA and affect how it works.**

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

You may need different amounts of your medicines or to stop taking them for a few days or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking PEMETREXED EVER PHARMA.

## 4. HOW DO I USE PEMETREXED EVER PHARMA?

### How much to take / use

- PEMETREXED EVER PHARMA will be given to you by a doctor and will decide the dosage of pemetrexed you should take. This will depend on your condition and other factors, such as your weight.
- Pemetrexed is given as an infusion (drip) into your veins over a 10 minute period.
- 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.
- When treating certain cancers, you may also be given other chemotherapy medicines.
- Never inject Pemetrexed by yourself. Always let your doctor or nurse do this.
- Your doctor or nurse will inject pemetrexed for you.

### If you use too much PEMETREXED EVER PHARMA

As PEMETREXED EVER PHARMA 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 EVER PHARMA immediately tell your doctor or nurse or go to the Emergency Department at your nearest hospital.

**You should immediately:**

phone the Poisons Information Centre

(by calling 13 11 26), or

contact your doctor, or go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. WHAT SHOULD I KNOW WHILE USING [PEMETREXED EVER PHARMA]?

### Things you should 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 receiving pemetrexed.**

- If you are going to have surgery, tell the surgeon or anesthetist that you are receiving Pemetrexed.
- 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 pemetrexed.
- 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 you should not do

Do not stop receiving PEMETREXED EVER PHARMA because you are feeling better, unless advised by your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how PEMETREXED EVER PHARMA 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.

### Looking after your medicine

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 stays below 25 °C.

## 6. Are there any side effects?

This medicine is to help people with mesothelioma or non-small cell lung cancer, but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

**See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.**

### Less serious side effects

Less serious side effects	What to do
<p><b>GENERAL BODY</b></p> <ul style="list-style-type: none"> <li>fever or infection with a temperature, sweating or othersigns of infection</li> <li>fatigue</li> <li>drowsiness</li> <li>feeling dehydrated</li> <li>muscle weakness</li> </ul> <p><b>GASTROINTESTINAL</b></p> <ul style="list-style-type: none"> <li>Pain in stomach</li> <li>Upset stomach</li> <li>Nausea</li> <li>Loss of appetite</li> <li>Vomiting</li> <li>Diarrhoea</li> <li>Constipation</li> </ul> <p><b>KIDNEY/URINE</b></p> <ul style="list-style-type: none"> <li>dark urine</li> </ul> <p><b>EYE</b></p> <ul style="list-style-type: none"> <li>Conjunctivitis (red and itchy eyes with or without discharge and crusty eyelids)</li> </ul> <p><b>SKIN</b></p> <ul style="list-style-type: none"> <li>skin irritation,</li> <li>burning or</li> <li>prickling sensation</li> </ul> <p><b>RESPIRATORY</b></p> <ul style="list-style-type: none"> <li>coughing,</li> <li>difficulty breathing,</li> <li>wheezing caused by inflammation of the lung</li> </ul> <p>Additional side effects when used in combination with other chemotherapy agents.</p> <p><b>MOUTH</b></p> <ul style="list-style-type: none"> <li>Taste change</li> </ul> <p><b>GENERAL BODY</b></p> <ul style="list-style-type: none"> <li>Loss of feeling</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p><b>KIDNEY</b></p> <ul style="list-style-type: none"> <li>Kidney problems – passing little or no urine</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>GENERAL BODY</b></p> <ul style="list-style-type: none"> <li>Fever</li> <li>Infection with a temperature</li> <li>Sweating or other signs of infection</li> <li>Tiredness</li> <li>feeling faint or breathless</li> </ul> <p><b>MOUTH</b></p> <ul style="list-style-type: none"> <li>Pain</li> <li>Redness</li> <li>Selling</li> <li>Sore in mouth</li> </ul> <p><b>ALLERGY</b></p> <ul style="list-style-type: none"> <li>Signs of allergy, rash</li> <li>Itching</li> <li>Hives on skin</li> <li>Swelling of face, lips or tongue or other parts of body</li> <li>Shortness of breath</li> <li>Wheezing</li> <li>Trouble breathing</li> </ul> <p><b>SKIN/BODY</b></p> <ul style="list-style-type: none"> <li>Looking pale</li> <li>bleeding or bruising more easily than normal</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

In rare cases PEMETREXED EVER PHARMA 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 any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

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.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What PEMETREXED EVER PHARMA contains

<b>Active ingredient (main ingredient)</b>	Pemetrexed disodium hemipentahydrate
<b>Other ingredients (inactive ingredients)</b>	Trometamol Monothioglycerol Citric acid Sodium hydroxide and Hydrochloric acid may be added to adjust pH Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

**PEMETREXED EVER PHARMA does not contain preservatives or bacteriostatic agents.**

### What PEMETREXED EVER PHARMA looks like

PEMETREXED EVER PHARMA is provided in clear glass vials, containing a slightly yellow to green-yellow concentrate for solution for infusion.

PEMETREXED EVER PHARMA is available in three different strengths. Each strength is available in a pack size of 1 vial in a carton.

PEMETREXED EVER PHARMA 100 mg/4 mL concentrate for solution for infusion (AUST R 372327)

PEMETREXED EVER PHARMA 500 mg/20 mL concentrate for solution for infusion (AUST R 372328)

PEMETREXED EVER PHARMA 1000 mg/40 mL concentrate for solution for infusion (AUST R 372329)

## Who distributes PEMETREXED EVER PHARMA

InterPharma Pty Ltd  
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