

PEMETREXED ACCORD

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 being given Pemetrexed Accord?

Pemetrexed Accord contains the active ingredient pemetrexed (as disodium). Pemetrexed Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. Pemetrexed Accord 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 being given Pemetrexed Accord?](#) in the full CMI.

2. What should I know before I am given Pemetrexed Accord?

Do not use if you have ever had an allergic reaction to any medicine containing pemetrexed 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 am given Pemetrexed Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pemetrexed Accord 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 will I be given Pemetrexed Accord?

Pemetrexed Accord will be given to you by a doctor or a nurse.

More instructions can be found in Section [4. How will I be given Pemetrexed Accord?](#) in the full CMI.

5. What should I know while being given Pemetrexed Accord?

Things you should do	<ul style="list-style-type: none">• Be sure to keep all your doctor's appointments.• Tell any other doctors, dentists, and pharmacists who treat you that you are being given Pemetrexed Accord.• If you become pregnant while you are being given this medicine, tell your doctor immediately.• 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
Driving or using machines	Be careful driving or operating machinery until you know how Pemetrexed Accord 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.

For more information, see Section [5. What should I know while being given Pemetrexed Accord?](#) in the full CMI.

6. Are there any side effects?

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.

Some of the serious side effects are:

- Allergic reaction – some symptoms may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of body; rash, itching or hives on skin
- chest pain or fast heartbeat
- fever or infection with a temperature sweating or other signs of infection
- tiredness
- feeling faint or breathless
- looking pale
- bleeding or bruising more easily than normal
- bleeding from the gums, nose or mouth, any bleeding that will not stop, reddish or pinkish urine, unexpected bruising
- mouth pain, redness, swelling, sores in the mouth

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 ACCORD

Active ingredient(s): *Pemetrexed (as disodium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pemetrexed Accord. **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 Accord.**

Where to find information in this leaflet:

- [1. Why am I being given Pemetrexed Accord?](#)
- [2. What should I know before I am given Pemetrexed Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Pemetrexed Accord?](#)
- [5. What should I know while being given Pemetrexed Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Pemetrexed Accord?

Pemetrexed Accord contains the active ingredient pemetrexed. Pemetrexed Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear of these being called chemotherapy medicines.

Pemetrexed Accord 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.

Pemetrexed Accord affects enzymes within cancer cells to kill the cancer cells or prevent them growing and multiplying.

Pemetrexed Accord may be used alone or in combination with other medicines to treat cancer.

Your doctor, however, may prescribe Pemetrexed Accord for another purpose.

2. What should I know before I am given Pemetrexed Accord?

Warnings

You must not be given Pemetrexed Accord if:

- you have an allergy to pemetrexed or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you have or have had:

- kidney problems. Depending on the severity of your condition, your doctor may choose not to treat you with Pemetrexed Accord
- have high blood pressure or diabetes as these conditions may increase your risk of developing kidney

problems while being treated with Pemetrexed Accord.

- have heart problems or other cardiovascular risk factors (such as high cholesterol levels, are a smoker) as these may increase your risk of experiencing a heart attack or stroke while being treated with Pemetrexed Accord

Tell your doctor if you are scheduled for any vaccinations or have recently been vaccinated. Some vaccines (live vaccines) should not be given while you are being treated with Pemetrexed Accord. Check with your doctor before receiving any vaccines.

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

Tell your doctor if you:

- are pregnant, or intend to become pregnant
- are breastfeeding or plan to breastfeed

Like most medicines used to treat cancer, Pemetrexed Accord is not recommended for use during pregnancy. Your doctor will discuss with you the risks and benefits of having Pemetrexed Accord during pregnancy.

You should not breast-feed your child during your treatment with Pemetrexed Accord.

Children 18 years of age and under

Pemetrexed Accord 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 Accord. 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 Accord dose. This should be continued throughout your therapy cycles and for at least three weeks following completion of Pemetrexed Accord treatment.

Your doctor should also advise you to have a vitamin B12 injection during the week before your first dose of Pemetrexed Accord. 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 and Pemetrexed Accord may interfere with each other. These include:

- medicines used to treat arthritis or pain from inflammation such as ibuprofen or other non-steroidal anti-inflammatory medicines (NSAIDs)
- medicines used to treat heartburn and acid regurgitation such as omeprazole, esomeprazole, lansoprazole, pantoprazole and rabeprazole (proton pump inhibitors).
- medicines used to treat infections such as penicillin.
- medicines used to treat gout or gouty arthritis such as probenecid.

These medicines and treatments may be affected by Pemetrexed Accord or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Pemetrexed Accord.

4. How will I be given Pemetrexed Accord?

How much will be given

Your doctor will decide on what dose you will receive. This depends on your condition and other factors, such as your weight.

When will Pemetrexed Accord be given

Pemetrexed Accord 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.

Pemetrexed Accord 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 Accord. 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 receive too much Pemetrexed Accord

Since Pemetrexed Accord is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Pemetrexed Accord.

You should immediately:

- phone the Poisons Information Centre (13 11 26), or
- contact your doctor, nurse or pharmacist.

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

5. What should I know while being given Pemetrexed Accord?

Things you must do

Be sure to keep all your doctor's appointments so that your progress can be checked.

Always take your daily folate supplement a multivitamin containing folate once daily for at least five days in the week before your first dose should continue throughout your treatment cycles and for at least 3 weeks following completion of the treatment or until your doctor tells you to stop.

Your doctor should advise you to have a vitamin B12 injection during the week before your first dose of Pemetrexed Accord. Additional vitamin B12 injections should be given once every three treatment cycles. Your doctor may advise you to take an oral corticosteroid such as dexamethasone to reduce the likelihood and severity of skin rashes.

Your doctor may advise you to take a medicine to help reduce nausea (antiemetic).

Your doctor may also advise you to receive an infusion (drip) of fluid into your veins for hydration.

Things you should do

- If you become pregnant while you are being given Pemetrexed Accord, tell your doctor immediately.
- Tell any other doctors, dentists, and pharmacists who treat you that you are being given Pemetrexed Accord.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are receiving this medicine. It may affect other medicines used during surgery.
- Keep your doctor's appointments. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving Pemetrexed Accord.

Driving or using machines

Be careful driving or operating machinery until you know how Pemetrexed Accord 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

The hospital will store Pemetrexed Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Pemetrexed Accord that may be left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

Common side effects

Common side effects	What to do
<p>GENERAL</p> <ul style="list-style-type: none"> tiredness, sleepiness (fatigue) fever or infection with a temperature, sweating or other signs of infection drowsiness feeling thirsty/dehydrated muscle weakness hair loss abdominal, chest, back or leg pain build-up of fluid in lower legs and ankles <p>STOMACH</p> <ul style="list-style-type: none"> heartburn (typically a burning sensation that begins just below the breastbone and moves up towards the throat) indigestion (dyspepsia) – discomfort in the upper stomach pain in stomach, upset stomach nausea loss of appetite vomiting diarrhoea constipation <p>RESPIRATORY</p> <ul style="list-style-type: none"> coughing difficulty breathing wheezing caused by inflammation of the lung <p>EYES</p> <ul style="list-style-type: none"> conjunctivitis (red and itchy eyes with or without discharge and crusty eyelids) Blurred vision, sensitivity to light. <p>SKIN</p> <ul style="list-style-type: none"> skin irritation burning or prickling sensation <p>MOUTH</p> <ul style="list-style-type: none"> taste change pain, redness, swelling, pus or sores in your mouth sore throat difficulty swallowing <p>KIDNEY</p> <ul style="list-style-type: none"> kidney problems – passing little or no urine 	<p>Speak to your doctor if you have any of these common side effects and they worry you</p>

Serious side effects

Serious side effects	What to do
<p>ALLERGY</p> <p>Symptoms of allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of body; rash, itching or hives on skin</p> <p>BLOOD RELATED</p> <p>Symptoms of abnormal blood cell counts may include:</p> <ul style="list-style-type: none"> tiredness, weakness, feeling faint or dizzy breathlessness looking pale fever, chills, swollen lymph nodes, or other signs of infection ulcers in the mouth, or sore mouth or throat bleeding or bruising more easily than normal prolonged bleeding bleeding from your gums or nose, or blood in urine or stools. <p>LIVER</p> <p>Symptoms of liver impairment may include:</p> <ul style="list-style-type: none"> yellowing of the skin or eye swelling or pain in your abdomen (belly), swelling in your ankles and legs dark-coloured urine or light coloured stool loss of appetite frequent itchiness. <p>KIDNEY</p> <p>Symptoms of kidney impairment may include:</p> <ul style="list-style-type: none"> decreased urination (little to none) or dark urine pain when urinating build-up of fluid in your legs, ankles, and feet. <p>NERVOUS SYSTEM</p> <ul style="list-style-type: none"> numbness, prickling, or tingling in your hands/arms or feet/legs sharp, jabbing, or burning pain extreme sensitivity to touch, or loss of sensation lack of coordination, muscle weakness. <p>STOMACH</p> <p>Inflammation of the large intestines. Symptoms may include:</p> <ul style="list-style-type: none"> diarrhoea with blood or mucus constant urge to have a bowel movement 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • bloating • stomach pain • fever. <p>CHEST</p> <ul style="list-style-type: none"> • difficulty breathing, shortness of breath that gets worse when active or lying down • a feeling of suffocation or drowning that worsens when lying down • dry cough, coughing up frothy or bloody mucus • chest pain • slow, fast, or irregular heartbeat. <p>SKIN</p> <ul style="list-style-type: none"> • a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Steven-Johnsons syndrome) • severe skin rash, which may blister and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge (Erythema multiforme) • severe skin rash, with redness, and peeling skin which may appear like a sunburn (Radiation recall) 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</p>

In rare cases Pemetrexed Accord 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

These side effects may differ when using Pemetrexed Accord in combination with another chemotherapy agent.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

The benefits and side effects of Pemetrexed Accord may take some time to occur. Therefore, even after you have finished your Pemetrexed Accord treatment you should tell your doctor or nurse immediately if you notice any of the side effects listed in this section.

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. 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 Accord contains

Active ingredient (main ingredient)	pemetrexed
Other ingredients (inactive ingredients)	mannitol hydrochloric acid, sodium hydroxide (pH adjustment)

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

What Pemetrexed Accord looks like

Pemetrexed Accord is a white to off white powder and is available in a glass vial. (100 mg: AUST R 222420, 500 mg: AUST R 222415, 1000 mg: AUST R 222419)

Who distributes Pemetrexed Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

www.accord-healthcare.com.au

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