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. 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	 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 heart beat
- 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 <u>6. Are there any side effects?</u> 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 and 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

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 <u>6. Are there any side effects?</u>

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.

Paediatric use

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

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

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 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 Accord.

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.

If you are about to have any blood tests, tell your doctor that you are receiving this medicine.

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 become pregnant while you are being given Pemetrexed Accord, tell your doctor immediately.

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
 GENERAL BODY fever or infection with a temperature, sweating or other signs of infection fatigue drowsiness feeling dehydrated muscle weakness hair loss abdominal, chest, back or leg pain 	Speak to your doctor if you have any of these common side effects and they worry you
 GASTROINTESTINAL pain in stomach upset stomach nausea loss of appetite vomiting diarrhoea constipation 	
 RESPIRATORY coughing difficulty breathing wheezing caused by 	
inflammation of the lung KIDNEY dark urine	
 conjunctivitis (red and itchy eyes with or without discharge and 	

crusty eyelids)		
SKIN		
skin irritationburning or prickling sensation		
Additional side effects when used in combination with other chemotherapy agents.		
GENERAL BODY		
loss of feeling		
моитн		
taste change		
KIDNEY		
kidney problems – passing little or no urine		

Serious side effects

Serious side effects	What to do
ALLERGY	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital
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	
GENERAL BODY	
 chest pain or fast heart beat 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 	
моитн	
painrednessswellingsores in the mouth	

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	pemetrexed
(main ingredient)	
Other ingredients	mannitol
(inactive ingredients)	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

This leaflet was prepared in November 2023.