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 SUN?

Pemetrexed SUN contains the active ingredient pemetrexed disodium. Pemetrexed SUN is used to treat mesothelioma and non-small cell lung cancer.

For more information, see Section 1. Why am I using Pemetrexed SUN? in the full CMI.

2. What should I know before I use Pemetrexed SUN?

Do not use if you have ever had an allergic reaction to Pemetrexed SUN 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 SUN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pemetrexed SUN 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 Pemetrexed SUN will be given?

- Your doctor will decide the dosage of Pemetrexed SUN you should take. This will depend on your condition and other factors, such as your weight.
- Pemetrexed SUN is given as an infusion (drip) into your veins over a 10 minute period.

More instructions can be found in Section <u>4. How do I use Pemetrexed SUN?</u> in the full CMI.

5. What should I know while using Pemetrexed SUN?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Pemetrexed SUN. 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 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.
Driving or using machines	Pemetrexed SUN 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 using Pemetrexed SUN? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pemetrexed SUN.

Call your doctor immediately or go to the Emergency Department at your nearest hospital if you experience the following side effects: 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.

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 SUN

Active ingredient(s): pemetrexed disodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pemetrexed SUN. 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 SUN.

Where to find information in this leaflet:

- 1. Why am I using Pemetrexed SUN?
- 2. What should I know before I use Pemetrexed SUN?
- 3. What if I am taking other medicines?
- 4. How do I use Pemetrexed SUN?
- 5. What should I know while using Pemetrexed SUN?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Pemetrexed SUN?

Pemetrexed SUN contains the active ingredient pemetrexed disodium.

Pemetrexed SUN 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.

It 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.

2. What should I know before I use Pemetrexed SUN?

Warnings

Do not use Pemetrexed SUN if:

- you are allergic to pemetrexed disodium, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- 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 <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

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

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

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

Paediatric Use

- 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 SUN. 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 SUN dose. This should be continued throughout your therapy cycles and for at least three weeks following completion of Pemetrexed SUN treatment.
- Your doctor should also advise you to have a vitamin B12 injection during the week before your first dose of Pemetrexed SUN. 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 SUN and affect how it works. These include:

 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 SUN.

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 SUN.

4. How Pemetrexed SUN will be given?

How much is given

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

How is it given

Pemetrexed SUN 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 SUN for you.

Never inject Pemetrexed SUN yourself.

Always let your doctor or nurse do this.

How often is it given

Pemetrexed SUN 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 SUN. 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 too much Pemetrexed SUN is given

As Pemetrexed SUN 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 SUN, immediately tell your doctor or nurse or go to the Emergency Department at your nearest hospital.

You may need urgent medical attention.

5. What should I know while using Pemetrexed SUN?

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 SUN.

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

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 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 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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pemetrexed SUN affects you.

Pemetrexed SUN 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.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pemetrexed SUN.

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

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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
 fatigue, drowsiness, fainting feeling dehydrated pain in the stomach, upset stomach, nausea, loss of appetite, vomiting diarrhoea, constipation, dark urine muscle weakness skin irritation, burning or prickling sensation 	Speak to your doctor if you have any of these less serious side effects and they worry you.

 hair loss conjunctivitis (red and itchy eyes with or without discharge and crusty eyelids) coughing, difficulty breathing, wheezing caused by inflammation of the lung 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.	

Serious side effects

Serious side effects	What to do
 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. The above list includes serious side effects which may require medical attention. 	Tell your doctor as soon as possible if you notice any of the following symptoms.
 In rare cases Pemetrexed SUN can cause inflammation of the colon (large bowel). diarrhoea with blood and mucus stomach pain fever 	Tell your doctor as soon as possible if you experience any of the following symptoms.
 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 	Call your doctor immediately or go to the Emergency Department at

medical attention or hospitalisation.	your nearest
	hospital.

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

Other side effects not listed here may 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 <u>www.tga.gov.au/reporting-problems</u>. 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 SUN contains

Active ingredient	Pemetrexed disodium
(main ingredient)	
Other ingredients	Mannitol
(inactive ingredients)	Hydrochloric acid and/or sodium hydroxide may be added to all presentations to adjust pH.

What Pemetrexed SUN looks like

Pemetrexed SUN is a white to off white powder and is available in a clear Type I glass vial container with a rubber stopper.

Vial stopper not made with natural rubber latex.

100mg/vial: AUST R 233814

500mg/vial: AUST R 233816

1000mg/vial: AUST R 233817

Who distributes Pemetrexed SUN

Sun Pharma ANZ Pty Ltd Suite 2.02, Level 2, 12 Waterloo Road Macquarie Park NSW 2113 Australia Tel no.: 1800 726 229 Email: <u>customerservice.aus@sunpharma.com</u>

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