

Pemetrexed – AFT

Pemetrexed powder for injection 100 mg

Pemetrexed powder for injection 500 mg

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Pemetrexed-AFT

This leaflet answers some common questions about Pemetrexed-AFT. 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 shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. The updated leaflet may contain important information about Pemetrexed-AFT and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pemetrexed-AFT against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Pemetrexed – AFT is used for

Pemetrexed - AFT 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.

Your doctor may have prescribed it for another reason.

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

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

Pemetrexed-AFT may be used in combination with other chemotherapy drugs.

Before you are given Pemetrexed – AFT

When you must not be given it

You should not be given Pemetrexed – AFT if you have an allergy to:

- any medicine containing pemetrexed disodium
- 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 face, lips, tongue or other parts of body
- rash, itching or hives on skin

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

Before you are given it

Tell your doctor if you have or have had the following medical condition:

- kidney problems

Tell your doctor if you are pregnant, plan to become pregnant or breast feeding.

Pregnancy and breast-feeding should be avoided during Pemetrexed-AFT treatment. Women of child-bearing age must use adequate contraception during treatment with pemetrexed. Your doctor can discuss with you the risks and benefits involved.

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.

If you have not told your doctor about any of the above, tell him/her before you take Pemetrexed-AFT.

Taking Premedication

Your doctor should advise you to take certain medicines or vitamin while taking Pemetrexed-AFT.

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-AFT 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-AFT. 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines maybe affected by Pemetrexed-AFT or may 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 being given Pemetrexed-AFT.

How Pemetrexed – AFT will be given

Follow all directions given to you by your doctor or pharmacist carefully.

How much is given

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

How it is given

Pemetrexed-AFT 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-AFT for you.

Never inject Pemetrexed-AFT yourself. Always let your doctor or nurse do this.

How often it is given

Pemetrexed-AFT 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-AFT. 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.

While you are being given Pemetrexed – AFT

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 receiving Pemetrexed-AFT.

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'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 driving or operating machinery until you know how Pemetrexed – AFT 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.

In case of overdose

If you take too much (overdose)

As Pemetrexed-AFT is given to you under the supervision of your doctor, it is unlikely that you will have too much

However, you think that you or anyone else may have taken too much, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning

You may need urgent medical attention.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while

you are being given Pemetrexed – AFT.

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. 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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, pharmacist or nurse as soon as possible if you notice any of the following and they worry you:

- 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
- 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.

Tell your doctor as soon as possible if you notice any of the following:

- 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.

In rare cases Pemetrexed-AFT 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.

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 stays below 25 °C.

Product description

What it looks like

Pemetrexed-AFT is a white to off white powder and is available in a glass vial container with a rubber stopper.

Ingredients

Pemetrexed-AFT is supplied in 500 mg and 100 mg vials.

The 500 mg vial of Pemetrexed-AFT contains pemetrexed disodium equivalent to 500 mg pemetrexed and 500 mg of mannitol.

The 100 mg vial of Pemetrexed-AFT contains pemetrexed disodium equivalent to 100 mg pemetrexed and 106.4 mg of mannitol.

Hydrochloric acid and/or sodium hydroxide may be added to both presentations to adjust pH.

Supplier

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