

DBL™ Pemetrexed (as disodium) powder for injection

pemetrexed disodium (pem-e-TREX-ed dye-SOE-dee-um)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Pemetrexed (as disodium) powder for injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DBL™ Pemetrexed (as disodium) powder for injection against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What DBL™ Pemetrexed (as disodium) powder for injection is used for

DBL™ Pemetrexed (as disodium) powder for injection is used to treat:

- malignant pleural mesothelioma, a rare cancer of the lungs often related to exposure to asbestos
- non small cell lung cancer, a type of lung cancer

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also

hear of these being called chemotherapy medicines.

DBL™ Pemetrexed (as disodium) powder for injection affects enzymes within cancer cells, killing cancer cells or stopping them from growing and multiplying.

This medicine may be used in combination with other medicines used to treat cancer.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why DBL™ Pemetrexed (as disodium) powder for injection has been prescribed for you.

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

DBL™ Pemetrexed (as disodium) powder for injection is not recommended for use in children under the age of 18, as there is not enough information on its effects in children in this age group.

Before you are given DBL™ Pemetrexed (as disodium) powder for injection

When you must not be given it

Do not take DBL™ Pemetrexed (as disodium) powder for injection if you have an allergy to:

- any medicine containing pemetrexed disodium hemipentahydrate
- 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.

Before you are given it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

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

- liver problems
- kidney problems
- heart problems
- blood disorder with a reduced number of red cells, white blood cells or platelets
- diabetes
- high blood pressure

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using DBL™ Pemetrexed (as disodium)

powder for injection during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking DBL™ Pemetrexed (as disodium) powder for injection, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you have not told your doctor about any of the above, tell them before you start taking DBL™ Pemetrexed (as disodium) powder for injection.

Your doctor should advise you to take certain medicines or vitamins while taking DBL™ Pemetrexed (as disodium) powder for injection.

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 DBL™ Pemetrexed (as disodium) powder for injection dose. This should be continued throughout your therapy cycles and for at least three weeks following completion of DBL™ Pemetrexed (as disodium) powder for injection treatment.

Your doctor should also advise you to have a vitamin B12 injection during the week before your first dose of DBL™ Pemetrexed (as disodium) powder for injection. 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 and DBL™ Pemetrexed (as disodium) powder for injection 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).
- some vaccines (ask your doctor)

These medicines may be affected by DBL™ Pemetrexed (as disodium) powder for injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking DBL™ Pemetrexed (as disodium) powder for injection.

How DBL™ Pemetrexed (as disodium) powder for injection is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

DBL™ Pemetrexed (as disodium) powder for injection may be given alone or in combination with other drugs.

Several courses of DBL™ Pemetrexed (as disodium) powder for injection therapy may be needed depending on your response to treatment.

Ask your doctor if you want to know more about the dose of

DBL™ Pemetrexed (as disodium) powder for injection you receive.

How it is given

DBL™ Pemetrexed (as disodium) powder for injection is given as a slow injection into a vein. DBL™ Pemetrexed (as disodium) powder for injection must only be given by a doctor or nurse.

DBL™ Pemetrexed (as disodium) powder for injection is given as an infusion (drip) into your veins, over 10 minutes.

How long it is given

DBL™ Pemetrexed (as disodium) powder for injection is usually given once every three weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need. Before each infusion you will have samples of your blood taken to check that you have enough blood cells to receive DBL™ Pemetrexed (as disodium) powder for injection. 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.

Overdose

As DBL™ Pemetrexed (as disodium) powder for injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given DBL™ Pemetrexed (as disodium) powder for injection, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of a DBL™ Pemetrexed (as disodium) powder for injection overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are using DBL™ Pemetrexed (as disodium) powder for injection

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.

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

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking DBL™ Pemetrexed (as disodium) powder for injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking DBL™ Pemetrexed (as disodium) powder for injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are having DBL™ Pemetrexed (as disodium) powder for injection.

If you become pregnant while taking DBL™ Pemetrexed (as disodium) powder for injection, tell your doctor.

DBL™ Pemetrexed (as disodium) powder for injection can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Pemetrexed (as disodium) powder for injection affects you.

This medicine may cause tiredness or drowsiness in some people. Make sure you know how you react to DBL™ Pemetrexed (as disodium) powder for injection before you drive a car, operate machinery, or do anything else that could be dangerous.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking DBL™ Pemetrexed (as disodium) powder for injection.

Like other medicines that treat cancer DBL™ Pemetrexed (as disodium) powder for injection may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

medical treatment if you get some of the side effects.

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

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

- fatigue, drowsiness
- high temperature
- rash
- sore throat
- feeling dehydrated
- pain in the stomach, upset stomach, nausea, loss of appetite, vomiting, indigestion
- diarrhoea, constipation
- muscle weakness
- skin irritation, burning or prickling sensation
- hair loss
- conjunctivitis (red and itchy eyes with or without discharge and crusty eyelids).

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.

These are the more common side effects of DBL™ Pemetrexed (as disodium) powder for injection.

Tell your doctor or nurse 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

- coughing, difficulty breathing, wheezing caused by inflammation of the lung.

In rare cases DBL™ Pemetrexed (as disodium) powder for injection 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.

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

After using DBL™ Pemetrexed (as disodium) powder for injection

Storage

DBL™ Pemetrexed (as disodium) powder for injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25 °C.

Product description

What it looks like

DBL™ Pemetrexed (as disodium) powder for injection is a white to either light yellow or green yellow powder available in sterile single use 100 mg, 500 mg or 1000 mg vials.

Ingredients

Active ingredients:

- pemetrexed disodium hemipentahydrate

Other ingredients

- mannitol

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

DBL™ Pemetrexed (as disodium) powder for injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Pemetrexed (as disodium) powder for injection is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd
 ABN 50 008 422 348
 38-42 Wharf Road
 West Ryde NSW 2114
 Australia

Toll Free number:
 1800 675 229

DBL™ Pemetrexed (as disodium) powder for injection is available in the following strengths:

100 mg, AUST R 182046

500 mg, AUST R 182045

1000 mg AUST R 228194

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