

DOCETAXEL EBEWE

Docetaxel Concentrated Injection Vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Docetaxel Ebewe.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet, you may need to read it again.

It is important to remember that Docetaxel Ebewe is a **PRESCRIPTION ONLY MEDICINE**.

Docetaxel Ebewe will only be given to you by specially trained personnel in a hospital environment.

What Docetaxel Ebewe is used for

Docetaxel Ebewe is used to treat breast cancer, ovarian cancer, some types of lung cancer and prostate cancer.

Docetaxel Ebewe works by stopping cells from growing and multiplying.

Docetaxel Ebewe belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

Your doctor may have prescribed Docetaxel Ebewe for another reason. Ask your doctor if you have any questions about why Docetaxel Ebewe has been prescribed for you.

You may have previously been given another medicine to treat your breast, ovarian, lung or prostate cancer. However, your doctor has now decided to treat you with Docetaxel Ebewe.

Docetaxel Ebewe may be used alone or in combination with other medicines to treat cancer.

Docetaxel Ebewe is not addictive.

Before you are given Docetaxel Ebewe

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

Docetaxel is not recommended for use in children.

When you must not be given this medicine:

You must not be given this medicine if you have had an allergic reaction to Docetaxel Ebewe or to any of the ingredients listed at the end of this leaflet (see **Product Description).**

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin
- dizziness or light-headedness
- back pain

Do not have Docetaxel if you have, or have had, any of the following medical conditions:

- severe liver problems
- blood disorder with a reduced number of white blood cells

You must not be given this medicine if the packaging is torn or shows signs of tampering.

You must not be given this medicine after the expiry date printed on the pack.

Before you are given this medicine

Tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

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

- severe liver problems
- blood disorder with a reduced number of white blood cells

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

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

Like most medicines used to treat cancer, Docetaxel Ebewe is not recommended to be given during pregnancy. If there is a need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks involved.

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

It is recommended that you do not breast-feed while you are receiving Docetaxel Ebewe, as it is not known whether Docetaxel passes into breast milk.

If you are not sure whether any of these apply to you, check with your doctor or pharmacist.

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

Some medicines may be affected by Docetaxel Ebewe or may affect how it works. These include:

- other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system, including cyclosporin
- some medicines used to treat bacterial infections, including erythromycin

- ketoconazole - a medicine used to treat fungal infections
- nifedipine - medicine used to treat high blood pressure and angina

These medicines may be affected by Docetaxel, 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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while having Docetaxel.

Your doctor and health care professional may have more information on medicines to be careful with or avoid while being given Docetaxel Ebewe.

How Docetaxel Ebewe is given

How it is given

This medicine is given as an infusion (drip) into your veins over a 60 minute period.

Your doctor or nurse will inject the medicine for you. **Never inject this medicine yourself. Always let your doctor or nurse do this.**

Before you are given your Docetaxel Ebewe infusion your doctor should:

- Prescribe you an oral corticosteroid (e.g. dexamethasone) to help stop or reduce the severity of certain side effects. For breast, lung and ovarian cancer, this medicine is usually taken for three days (one day before, the day of and the day after your infusion). These medicines are very important. For prostate cancer, this is

usually taken on the day of the infusion (12 hours, 3 hours and 1 hour before your infusion).

- Test your blood to see how many white blood cells you have. If they are too low, your infusion may be delayed
- Test your blood for levels of liver enzymes. If these levels are high your doctor may reduce your dose or decide you should not have a Docetaxel Ebewe infusion at that time.

Ask your doctor or pharmacist if you have any questions on these medicines or tests.

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 and height.

The usual dose of Docetaxel Ebewe is 75 to 100mg/m² which is based on your body size (m²).

When Docetaxel Ebewe is given in combination with capecitabine (another medicine used for the treatment of breast cancer) the usual dose of Docetaxel Ebewe is 75 mg/m².

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

How often it will be given

Docetaxel is given every 3 weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

In Case of Overdose

As Docetaxel Ebewe 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 Docetaxel Ebewe, tell your doctor immediately.

While you are being given Docetaxel Ebewe

Things you MUST do:

- **Be sure to keep all of your doctor's appointments.**
It is important to have your follow-up doses/cycles/infusions of Docetaxel Ebewe at the appropriate times to get the best effects from your treatments. Your doctor may also 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 all doctors and health care professionals who are treating you that you are being given Docetaxel Ebewe.**
- **If you are about to be started on any new medicine, tell your doctor or health care professional that you are being given Docetaxel Ebewe.**
- **Tell your doctor if you become pregnant while you are being given Docetaxel Ebewe.**

Docetaxel 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,**

pain in the lower back or side or you 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.**

Docetaxel may cause fluid retention which means the body is holding extra water. If this fluid retention is in the chest or around the heart it can be life-threatening. If you notice swelling in the feet and legs or a slight weight gain, inform your doctor or nurse.

In most cases, fluid retention will go away within weeks or months after your treatments are completed.

Things you must not do

Do not have Docetaxel Ebewe to treat any other complaints unless your doctor or pharmacist tells you to.

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Docetaxel Ebewe.

Like other medicines that treat cancer, Docetaxel Ebewe may have unwanted side effects,

some of which may be serious. You may need medical treatment if you experience some of the side effects.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- irritation, pain, swelling or colouring around the needle during infusion
- high temperature
- stomach pain or discomfort
- feeling sick, upset stomach or vomiting
- mild diarrhoea
- constipation
- inflammation of the food pipe (oesophagus)
- whitening or darkening of the skin or nails
- loosening of the nails
- unusual hair loss or thinning
- joint pain or swelling
- aching muscles, muscle tenderness or weakness not caused by exercise
- unusual tiredness or weakness
- confusion
- mild swelling of hands, ankles and feet
- weight gain
- pins and needles or a burning or tingling feeling in hands or feet
- redness or rash around previous radiation site (if you have had radiotherapy)
- back pain
- decreased appetite
- high blood pressure(hypertension)

- low blood pressure (hypotension)
- temporary visual disturbances, which mostly occur when you are being infused with Docetaxel Ebewe

These are the more common side effects of Docetaxel Ebewe.

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

- infections
- frequent infections with fever, severe chills, sore throat or mouth ulcers - especially 5-7 days after receiving a Docetaxel infusion
- sore red mouth or vagina
- severe diarrhoea
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- breathing problems, shortness of breath or difficulty in breathing
- coughing
- change in the rhythm or rate of your heart beats (palpitations)
- pain in muscles
- flushed, dry skin, irritability and confusion
- passing little or no urine, drowsiness, nausea, vomiting and breathlessness
- fainting
- yellowing of the skin or eyes, also called jaundice
- flaking of the skin
- chest pain / heart attack
- excessive watery discharge from the eyes
- trouble with your hearing, or some loss of hearing
- sudden and severe swelling or pain in the joints or rash

Tell your doctor, nurse or pharmacist immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- convulsions, fits or seizures
- ulcer in the stomach or intestine - vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions or bloody diarrhoea
- difficulty in breathing
- sudden swelling of the leg/arm which may be due to blood clots.

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

Please consult your doctor for possible side effects that may be caused by using Docetaxel Ebewe with another chemotherapy agent.

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.

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

After using Docetaxel Ebewe

Storage

Docetaxel Ebewe will be stored appropriately at the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product Description

What it looks like

Docetaxel Ebewe is a clear, colourless to pale yellow solution, supplied in a clear glass vial.

Ingredients

Active Ingredients:

Docetaxel Ebewe contains the active ingredient docetaxel 10mg/mL

Other ingredients:

Docetaxel Ebewe also contains anhydrous citric acid, macrogol 300, polysorbate 90 and ethanol.

Manufacturer

Docetaxel Ebewe is made by: EBEWE Pharma Ges.m.b.H. Nfg. KG A-4866 Unterach Austria

Sponsor

Docetaxel Ebewe is distributed in Australia by: InterPharma Pty Ltd Suite 3, 14 Sydney Road Manly NSW 2095

Distributed in New Zealand by: InterPharma (NZ) Ltd c/-Pharmaco (NZ) Ltd 4 Fisher Crescent, Mt Wellington

Auckland

Docetaxel Ebewe can be identified by an Australian Register Number, which is found on the packaging:

AUST R 153372 Docetaxel Ebewe 20mg/2mL in 2mL glass vial.

AUST R 153373 Docetaxel Ebewe 80mg/8mL in 12mL glass vial.

This leaflet was prepared in Jan 2010