

DOCETAXEL ACCORD

Docetaxel Concentrated Injection 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Docetaxel Accord.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Docetaxel Accord is used for

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

Docetaxel Accord works by stopping cells from growing and multiplying.

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

Your doctor, however, may prescribe Docetaxel Accord for another purpose.

Ask your doctor, nurse or pharmacist if you have any questions about why Docetaxel Accord has been prescribed for you.

You may have probably taken another

medicine to treat your breast, ovarian, lung, head and neck or prostate cancer. However, your doctor has now decided to treat you with Docetaxel Accord.

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

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

Docetaxel Accord is not addictive.

Docetaxel Accord is not recommended for use in children.

Before you are given it

When you must not be given it

Do not receive Docetaxel Accord if you have an allergy to docetaxel, paclitaxel or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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 receive Docetaxel Accord 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

Do not receive it if you are pregnant or intend to become pregnant either

during treatment or in the three months following the last dose of Docetaxel Accord.

Like most medicines used to treat cancer, Docetaxel Accord is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not receive it if you are breastfeeding or planning to breastfeed.

It is not known if Docetaxel Accord passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not receive it after the expiry date (EXP) printed on the carton.

If you receive it after the expiry date has passed, it may not work as well.

Do not receive it if the packaging is damaged or shows signs of tampering.

If you are not sure whether you should start having Docetaxel Accord, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

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

Like most medicines of this kind, Docetaxel Accord is not recommended to be used during pregnancy. Your

doctor will discuss the risks and benefits of being given it if you are pregnant.

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

It is not known whether Docetaxel Accord passes into breast milk. Your doctor will discuss the risks and benefits of being given it if you are breast-feeding or planning to breast-feed.

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

- liver problems
- blood disorder with a reduced number of white blood cells
- heart problems
- hearing problems
- epilepsy

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 plan to have surgery.

If you have not told your doctor about any of the above, tell them before you are given Docetaxel Accord.

Taking other medicines or treatments

Tell your doctor, nurse 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 Docetaxel Accord may interfere with each other. 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
- Some medicines called corticosteroids, such as phenobarbitone
- Medicines used to treat people with epilepsy
- Medicines used to treat or prevent HIV or Hepatitis C viral infections, such as ritonavir

These medicines and treatments may be affected by Docetaxel 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.

Your doctor, nurse or pharmacist has more information on medicines to be careful with or to avoid while being given Docetaxel Accord.

How it is given

Docetaxel Accord should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment.

Docetaxel Accord is for single use in one patient only. Any unused residue should be discarded.

Before you are given your Docetaxel Accord 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, ovarian, and head and neck, 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 Accord 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, height, kidney function and other chemotherapy medicines you may be given.

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

Docetaxel may be given alone or in combination with other medicines.

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

How it is given

Docetaxel Accord is given as an infusion (drip) into your veins, over 1 hour.

How long it will be given

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

If you forget to take it

As Docetaxel Accord is given to you under supervision of your doctor in a hospital or clinic environment, at scheduled appointments it is unlikely you will forget to take it. However please see your doctor as soon as possible if you miss your appointment.

If you receive too much (Overdose)

As Docetaxel Accord 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 unexpected or worrying side effects after being given Docetaxel Accord, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. In case of overdose, immediately phone your doctor or the National Poisons Centre (0800 POISON or 0800 764 766). Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being given it

Things you must do

Be sure to keep all your doctor's appointments.

It is important to have your follow-up doses/cycles/infusions of Docetaxel Accord 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 the doctors, dentists, and pharmacists who are treating you that you are being given Docetaxel Accord.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are being given Docetaxel Accord.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Docetaxel Accord.

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

Docetaxel Accord 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 or nurse 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.

If you notice swelling in the feet and legs or a slight weight gain, inform your doctor or nurse.

Docetaxel Accord 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. 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 Accord to treat any other complaints unless your doctor tells you to.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the

benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

If you are over 60 years of age you may have an increased chance of getting side effects.

It helps most people with breast, ovarian, lung, head and neck or prostate cancer, but it may have unwanted side effects in a few people.

Tell your doctor, nurse or pharmacist if you notice any of the following 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 or feeling that you are about to faint, which mostly occur when you are being infused with Docetaxel Accord

These are the more common side effects of Docetaxel Accord.

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 Accord infusion
- sore red mouth or vagina or swelling in these areas
- severe diarrhoea
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- breathing problems, shortness of breath or difficulty in breathing
- coughing, wheezing
- 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
- red, scaly patches of the skin especially around the cheeks and nose
- raised lumps on the skin which looks like scalding
- hardening 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

These may be serious side effects.

You may need medical attention.

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

- 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.

These side effects may differ when using Docetaxel Accord in combination with another chemotherapy agent.

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

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

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

After being given it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or pharmacist.

Storage

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

Product Description

What it looks like

Docetaxel Accord single-dose vials contain a pale yellow to brownish-yellow solution. It is available in 3 presentations; 20 mg/1 mL, 80 mg/4 mL and 160 mg/8 mL in single packs.

Docetaxel Accord concentrate vial is injected into an infusion bag. The infusion bag is then sent to the Chemotherapy Unit ready for your infusion.

Ingredients

Active Ingredient: docetaxel

Inactive ingredients:

Citric acid

Ethanol anhydrous

Polysorbate 80.

Your doctor, nurse or pharmacist can inform you what other ingredients are in your infusion bag.

Docetaxel Accord does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Name and Address of the Sponsor

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