

DOCETAXEL ACCORD

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 being given Docetaxel Accord?

Docetaxel Accord contains the active ingredient Docetaxel. Docetaxel Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. It 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.

For more information, see Section [1. Why am I using Docetaxel Accord?](#) in the full CMI.

2. What should I know before I am given Docetaxel Accord?

Do not use if you have ever had an allergic reaction to any medicine containing docetaxel, paclitaxel 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 am given Docetaxel Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Docetaxel Accord 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 will I be given Docetaxel Accord?

Docetaxel Accord will be given to you by a doctor or a nurse.

More instructions can be found in Section [4. How will I be given Docetaxel Accord?](#) in the full CMI.

5. What should I know while being given Docetaxel Accord?

Things you should do	• Be sure to keep all your doctor's appointments. • Tell any other doctors, dentists, and pharmacists who treat you that you are being given Docetaxel Accord. • If you become pregnant while you are being given this medicine, tell your doctor immediately. • Avoid people who have infections. • Be careful when using a toothbrush, toothpick or dental floss. • 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.
Driving or using machines	Be careful driving or operating machinery until you know how Docetaxel Accord affects you.
Alcohol	Docetaxel Accord contains alcohol.

For more information, see Section [5. What should I know while being given Docetaxel Accord?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the very serious side effects are:

- 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
- redness of the skin studded with pimples containing fluid or pus
- hallucinations or delirium
- 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, rapid and/or shallow breathing
- sudden swelling of the leg/arm which may be due to blood clots
- pain, pressure or tightness in the chest, arms, neck, jaw or back that may occur together with nausea, dizziness or cold sweats
- fainting
- fever with diarrhoea and or vomiting, painful cramping.

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.

DOCETAXEL ACCORD

Active ingredient(s): *Docetaxel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Docetaxel Accord. **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 Docetaxel Accord.**

Where to find information in this leaflet:

- [1. Why am I being given Docetaxel Accord?](#)
- [2. What should I know before I am given Docetaxel Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Docetaxel Accord?](#)
- [5. What should I know while being given Docetaxel Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Docetaxel Accord?

Docetaxel Accord contains the active ingredient Docetaxel. Docetaxel Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear of these being called chemotherapy medicines.

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

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

2. What should I know before I am given Docetaxel Accord?

Warnings

You must not be given Docetaxel Accord if:

- you have an allergy to docetaxel, paclitaxel or any of the ingredients listed at the end of this leaflet.
- severe liver problems
- you are pregnant or intend to become pregnant either during treatment or in the three months following the last dose of Docetaxel Accord

Docetaxel Accord is not recommended for use in children.

Tell your doctor if you have or have had:

- liver problems
- blood disorder with a reduced number of white blood cells
- epilepsy
- an infection or high temperature. Your doctor may

decide to delay your treatment until the infection has gone

Tell your doctor if you plan to have surgery.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Females

This medicine should not be used if you are pregnant or intend to become pregnant.

You should use a reliable method of contraception during treatment and for at least 6 months after your last dose.

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

Do not breastfeed during treatment with this medicine and for 1 week after your last dose.

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

You should not breast-feed your child during your treatment with Docetaxel Accord and for one week after the last dose. Docetaxel Accord may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Males

If you are with a female partner who can become pregnant, you should use a reliable method of contraception during treatment with Docetaxel Accord and for at least 4 months after your last dose.

You should seek advice from your doctor on preserving sperm before starting treatment.

Genetic Counselling

Both males and females should discuss the need for individual genetic counselling with their doctor if you decide to have a child after treatment.

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 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, vinorelbine, vinblastine
- some medicines used to treat bacterial infections (antibiotics), including erythromycin and clarithromycin
- medicines used to treat fungal infections include ketoconazole, itraconazole and voriconazole

- medicine used to treat high blood pressure and angina - nifedipine
- medicine used to lower cholesterol - clofibrate,
- medicines called corticosteroids such as dexamethasone
- medicines used to treat people with epilepsy, including phenobarbitone
- medicines used to treat or prevent HIV or Hepatitis C viral infections, including 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Docetaxel Accord.

4. How will I be given Docetaxel Accord?

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 if you have any questions on these medicines or tests.

How much will be 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 treated with.

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

Several courses of docetaxel therapy may be needed depending on your response to treatment. Additional treatment may not be repeated until your blood cell numbers return to acceptable levels.

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

When will Docetaxel Accord be given

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

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 receive too much Docetaxel Accord

Since Docetaxel Accord is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Docetaxel Accord.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, nurse or pharmacist.
- go to the Emergency Department at your nearest hospital

You may need urgent medical attention.

5. What should I know while being given Docetaxel Accord?

Things you must do

Be sure to keep all your doctor's appointments.

It is important to have your follow-up doses/cycles 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.

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

Tell any other doctors, dentists, and pharmacists who treat you 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.

Inform your doctor or nurse if you notice any of the following:

- flushing, rash (with or without itchiness), tight chest, back pain, shortness of breath, fever, chills
- abnormal bleeding or bruising
- abdominal pain or tenderness or severe diarrhoea
- changes in hearing or abnormal sounds in the ears
- changes in vision
- painful red areas of the skin, pustules or blisters, or skin peeling
- problems breathing
- numbness, tingling in the hands or feet and loss of reflexes
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Docetaxel Accord affects you.

Docetaxel Accord may cause dizziness, light-headedness, tiredness, and drowsiness in some people. Make sure you know how you react to docetaxel before you drive a car, operate machinery, or do anything else that could be dangerous and do not do so if not safe.

Docetaxel Accord also contains alcohol, which may affect the ability to safely drive or use machinery.

Alcohol

Docetaxel Accord contains ethanol (alcohol).

The alcohol content in this medication is harmful to those who suffer from alcohol dependency. The alcohol content in this medication should be considered in patients suffering from epilepsy or liver disease.

Speak to your doctor if you may drink alcohol while having treatment with Docetaxel Accord.

Looking after your medicine

The hospital will store Docetaxel Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Docetaxel Accord that may be left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Less serious side effects	What to do
Body as a whole: • high temperature • confusion • headache • dizziness • joint pain or swelling • aching muscles, muscle tenderness or weakness not caused by exercise • unusual tiredness or weakness • mild swelling of hands, ankles and feet • pins and needles or a burning or tingling feeling in hands or feet • back pain • decreased appetite • weight gain Stomach related: • stomach pain or discomfort • feeling sick, upset stomach or vomiting • mild diarrhoea • constipation • indigestion, heartburn Nervous system related: • high blood pressure • Light-headedness, dizziness or fainting (due to low blood pressure) Respiratory system related • difficult or painful swallowing, • sore throat • dry mouth • nose bleeds, runny nose • food taste different, especially metallic Skin related • whitening or darkening of the skin or nails • loosening of the nails • unusual hair loss or thinning • redness or rash around previous radiation site (if you have had radiotherapy) Eye related: temporary visual disturbances or feeling that you are about to faint, which mostly occur when you are being infused with Docetaxel Accord Injection site related: • irritation, pain, swelling or colouring around the needle during infusion	Speak to your doctor if you have any of these common side effects and they worry you

Less serious side effects	What to do
Menstrual related: loss of, or irregular, periods (menstruation)	

Serious side effects

Serious side effects	What to do
Body as a whole: - frequent infections with fever, severe chills, sore throat or mouth ulcers - especially 5-7 days after receiving a Docetaxel Accord infusion - high temperature or an infections - being short of breath when exercising - tiredness - headaches - irritability and confusion - pain in muscles - passing little or no urine - sudden and severe swelling or pain in the joints - leg pain, tenderness or swelling. - dizziness and looking pale Stomach related: - nausea, vomiting - severe diarrhoea Respiratory system related - sore red mouth or vagina or swelling in these areas - breathing problems, shortness of breath or difficulty in breathing, rapid and/or shallow breathing - coughing, wheezing Nervous system related: - drowsiness - fainting Skin related - skin numbness or loss of feeling - skin that is red and warm - yellowing of the skin or eyes, also called jaundice - flaking or peeling 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 - flushed, dry skin Eye related: - excessive watery discharge from the eyes - blurry or “wavy” vision	Call your doctor straight away

Serious side effects	What to do
- disturbances to colour vision Hearing related: - trouble with your hearing, or some loss of hearing Heart related: - change in the rhythm or rate of your heart beats (palpitations) - chest pain / heart attack	

Very Serious side effects

Very serious side effects	What to do
Allergic reactions: 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 Skin related: - redness of the skin studded with pimples containing fluid or pus Whole body related: - convulsions, fits or seizures - sudden swelling of the leg/arm which may be due to blood clots - hallucinations or delirium - pain, pressure or tightness in the chest, arms, neck, jaw or back that may occur together with nausea, dizziness or cold sweats - fainting Stomach related: - 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 - fever with diarrhoea and or vomiting - painful cramping Respiratory related: - difficulty in breathing	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital

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

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

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

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.

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 www.tga.gov.au/reporting-problems. 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.
It is not addictive.

What Docetaxel Accord contains

Active ingredient (main ingredient)	docetaxel
Other ingredients (inactive ingredients)	citric acid ethanol anhydrous (alcohol) polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

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

What Docetaxel Accord looks like

Docetaxel Accord is a pale yellow to brownish-yellow solution supplied in a vial in single packs. (80 mg/4 mL: AUST R 209473, 160 mg/8 mL: AUST R 209465)

Who distributes Docetaxel Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

www.accord-healthcare.com.au

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