

Docetaxel Sandoz®

Docetaxel concentrated injection for infusion

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Docetaxel Sandoz.

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 this medicine 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.

You may need to read it again.

WHAT DOCETAXEL SANDOZ IS USED FOR

The name of the medicine is called Docetaxel Sandoz. It contains the active ingredient docetaxel. Docetaxel belongs to a group of medicines called antineoplastic or cytotoxic medicines. These may also be called chemotherapy medicines. It works by killing cancer cells and stopping cancer cells from growing and multiplying.

This medicine is used to treat

- breast cancer
- ovarian cancer
- some types of lung cancer
- head and neck cancer
- prostate cancer.

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

Your doctor may have prescribed Docetaxel Sandoz for another reason.

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

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine for children.

BEFORE YOU ARE GIVEN DOCETAXEL SANDOZ

When you must not be given Docetaxel Sandoz

Do not receive this medicine if you have an allergy to:

- Docetaxel, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

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
- back pain.

Do not receive Docetaxel Sandoz 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 this medicine if you are pregnant or intend to become pregnant either during treatment or in the three months following the last dose of docetaxel.

Like most medicines to treat cancer, this medicine is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of being given it if you are pregnant.

Do not breastfeed if you are given this medicine.

It is not known whether the active ingredient in Docetaxel Sandoz passes into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss the risks and benefits of being given it if you are breast feeding or are planning to breast feed.

Do not give this medicine to a child.

Safety and effectiveness in children have not been established.

Do not receive this medicine after the expiry date printed on the vial or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, it may not work as well.

If you are not sure whether you should start receiving this medicine, talk to your doctor.

Before you are given Docetaxel Sandoz

Tell your doctor 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
- 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 plan to have surgery.

If you have not told your doctor about any of the above, tell him/her before you start receiving Docetaxel Sandoz.

Taking other medicines

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

Some medicines and Docetaxel Sandoz 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
- medicines used to used to treat or prevent viral infections, including ritonavir.

These medicines and treatments may be affected by Docetaxel Sandoz, 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 Sandoz.

HOW DOCETAXEL SANDOZ IS GIVEN

Docetaxel Sandoz should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment. Each vial is single use, to be used for one patient only on one occasion only.

Before you are given your Docetaxel Sandoz 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 cancer, this medicine is usually received 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 Sandoz infusion at that time.

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

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

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

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

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

How Docetaxel Sandoz is given

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

How long Docetaxel Sandoz will be given

Docetaxel Sandoz 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 (overdose)

As Docetaxel Sandoz 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 Sandoz, telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.

WHILE YOU ARE BEING GIVEN DOCETAXEL SANDOZ

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are being given Docetaxel Sandoz.

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

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

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

Docetaxel Sandoz 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 Sandoz 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.

Be sure to keep all your doctor's appointments.

It is important to have your follow-up doses/cycles/infusions of Docetaxel Sandoz 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.

Things you must not do

Do not have Docetaxel Sandoz to treat any other complaints unless your doctor tells you to.

Things to be careful of

The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving Docetaxel Sandoz by:

- flushing the toilet twice (with the toilet lid down) to dispose of any body fluids and waste
- wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet

- washing linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water
- placing soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage
- for sexual intercourse, use a barrier method such as a condom.

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.

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

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 Sandoz.

These are the more common side effects of Docetaxel Sandoz.

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, 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 Sandoz 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
- 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 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.

The above list includes 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 Sandoz with another chemotherapy agent.

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

Other side effects not listed above may also occur in some people.

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

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

AFTER BEING GIVEN DOCETAXEL SANDOZ

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

The Docetaxel Sandoz concentrate for infusion will be stored in the pharmacy or on the ward. The infusion is kept in a cool dry place, where the temperature stays below 25°C.

Disposal

The hospital staff will dispose of any unused Docetaxel Sandoz.

PRODUCT DESCRIPTION

What it looks like

Docetaxel Sandoz comes in 2 types of vials:

- Docetaxel Sandoz 20mg/2mL - 2mL clear glass vial with rubber stopper (latex free) and flip-off aluminium crimp, containing a clear pale yellow sterile solution.
- Docetaxel Sandoz 80mg/8mL - 8mL clear glass vial with rubber stopper (latex free) and flip-off aluminium crimp, containing a clear pale yellow sterile solution.

Available in packs of 1 vial.

The Docetaxel Sandoz concentrated injection for infusion vial is injected into an infusion bag/glass bottle ready for your infusion in the Chemotherapy Unit. The infusion bag/glass bottle is then sent to the Chemotherapy Unit ready for your infusion.

Ingredients

Active ingredients:

- Docetaxel Sandoz 20mg/2mL - 20mg docetaxel
- Docetaxel Sandoz 80mg/8mL - 80mg docetaxel

Inactive ingredients:

- Ethanol
- Polysorbate 80
- Citric Acid, anhydrous.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

Supplier

Sandoz Pty Ltd

ABN 60 075 449 553

Level 2, 19 Harris St

Pymont NSW 2009

Tel: 1800 634 500

Novartis New Zealand Ltd

Private Bag 65904 Mairangi Bay

Auckland 0754

New Zealand

Tel: 0800 354 335

This leaflet was prepared in October 2011.

Australian Register Numbers

Docetaxel Sandoz 20mg/2mL concentrated injection for infusion:

AUST R 170108

Docetaxel Sandoz 80mg/8mL

concentrated injection for infusion:

AUST R 170109