PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Docetaxel Seacross 20 mg/ml concentrate for solution for infusion
docetaxel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, hospital pharmacist or nurse.
- If you get any side effects talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Docetaxel Seacross is and what it is used for
2. What you need to know before you use Docetaxel Seacross
3. How to use Docetaxel Seacross
4. Possible side effects
5. How to store Docetaxel Seacross
6. Contents of the pack and other information

1. WHAT DOCETAXEL SEACROSS IS AND WHAT IT IS USED FOR

The name of this medicine is Docetaxel Seacross. Its common name is docetaxel.
Docetaxel is a substance derived from the needles of yew trees.
Docetaxel belongs to the group of anti-cancer medicines called taxoids.

Docetaxel Seacross has been prescribed by your doctor for the treatment of breast cancer, special forms of lung cancer (non-small cell lung cancer), prostate cancer, gastric cancer or head and neck cancer:
- For the treatment of advanced breast cancer, Docetaxel Seacross could be administered either alone or in combination with doxorubicin, or trastuzumab, or capecitabine.
- For the treatment of early breast cancer with or without lymph node involvement, Docetaxel Seacross could be administered in combination with doxorubicin and cyclophosphamide.
- For the treatment of lung cancer, Docetaxel Seacross could be administered either alone or in combination with cisplatin.
- For the treatment of prostate cancer, Docetaxel Seacross is administered in combination with prednisone or prednisolone.
- For the treatment of metastatic gastric cancer, Docetaxel Seacross is administered in combination with cisplatin and 5-fluorouracil.
- For the treatment of head and neck cancer, Docetaxel Seacross is administered in combination with cisplatin and 5-fluorouracil.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DOCETAXEL SEACROSS

You must not be given Docetaxel Seacross
- if you are allergic (hypersensitive) to docetaxel or any of the other ingredients of this medicine (listed in section 6).
- if the number of white blood cells is too low.
- if you have a severe liver disease.

Warnings and precautions
Before each treatment with Docetaxel Seacross, you will have blood tests to check that you have enough blood cells and sufficient liver function to receive Docetaxel Seacross.
In case of white blood cells disturbances, you may experience associated fever or

infections.

Tell your doctor, hospital pharmacist, or nurse immediately if you have abdominal pain or tenderness, diarrhoea, rectal haemorrhage, blood in stool or fever. These symptoms may be the first signs of a serious gastrointestinal toxicity, which could be fatal. Your doctor should address them immediately.

Tell your doctor, hospital pharmacist or nurse if you have vision problems. In case of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.

Tell your doctor, hospital pharmacist or nurse if you have experienced an allergic reaction to previous paclitaxel therapy.

Tell your doctor, hospital pharmacist or nurse if you have heart problems.

If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your doctor, hospital pharmacist or nurse immediately. Your doctor may stop your treatment immediately.

You will be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to Docetaxel Seacross administration and to continue for one or two days after it in order to minimise certain undesirable effects which may occur after the infusion of Docetaxel Seacross in particular allergic reactions and fluid retention (swelling of the hands, feet, legs or weight gain).

During treatment, you may be given other medicines to maintain the number of your blood cells.

Severe skin problems such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP) have been reported with Docetaxel:

- SJS/TEN symptoms may include blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.
- AGEP symptoms may include a red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever.

If you develop severe skin reactions or any of the reactions listed above, immediately contact your doctor or healthcare professional.

Tell your doctor, hospital pharmacist or nurse if you have kidney problems or high levels of uric acid in your blood before initiating Docetaxel.

Docetaxel Seacross contains alcohol. Discuss with your doctor if you suffer from alcohol dependency, epilepsy or liver impairment. See also section “Docetaxel Seacross contains ethanol (alcohol)” below.

Other medicines and Docetaxel Seacross

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription. This is because Docetaxel Seacross or the other medicine may not work as well as expected and you may be more likely to get a side effect. The amount of alcohol in this medicinal product may alter the effects of other medicines.

Pregnancy, breast-feeding and fertility

Ask your doctor for advice before being given any medicine.

Docetaxel Seacross must NOT be administered if you are pregnant unless clearly indicated by your doctor.

You must not become pregnant during treatment and for 2 months after end of treatment with this medicine. You must use an effective method of contraception during treatment and for 2 months after end of treatment, because Docetaxel Seacross may be harmful for the unborn baby. If pregnancy occurs during your treatment, you must immediately inform your doctor.

You must not breast-feed while you are treated with Docetaxel Seacross.

If you are a man being treated with Docetaxel Seacross you must not father a child and must use an effective method of contraception during treatment and for 4 months after end of treatment with this medicine. It is recommended to seek advice on conservation of sperm prior to treatment because docetaxel may alter male fertility.

Driving and using machines
The amount of alcohol in this medicinal product may impair your ability to drive or use machines. You may experience side effects of this medicine that may impair your ability to drive, use tools or operate machines (see section 4 Possible side effects). If this happens, do not drive or use any tools or machines before discussing with your doctor, nurse or hospital pharmacist.

Docetaxel Seacross contains ethanol (alcohol)
This medicinal product contains 50 vol % ethanol anhydrous (alcohol), i.e. 395 mg (0.5 ml) ethanol anhydrous per vial of 1 ml fill volume, equivalent to 10 ml beer or 4 ml wine per 1 ml vial, 1.58 g (2 ml) ethanol anhydrous per vial of 4 ml fill volume, equivalent to 40 ml beer or 17 ml wine per 4 ml vial, or 3.16 g (4 ml) ethanol anhydrous per vial of 8 ml fill volume, equivalent to 80 ml beer or 33ml wine per 8 ml vial.

Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, in children and high-risk groups such as patients with liver disease, or epilepsy.

The amount of alcohol in this medicinal product may have effects on the central nervous system (the part of the nervous system that includes the brain and spinal cord).

3. HOW TO USE DOCETAXEL SEACROSS

Docetaxel Seacross will be administered to you by a healthcare professional.

Usual dose
The dose will depend on your weight and your general condition. Your doctor will calculate your body surface area in square meters (m^2) and will determine the dose you should receive.

Method and route of administration
Docetaxel Seacross will be given by infusion into one of your veins (intravenous use). The infusion will last approximately one hour during which you will be in the hospital.

Frequency of administration
You should usually receive your infusion once every 3 weeks.

Your doctor may change the dose and frequency of dosing depending on your blood tests, your general condition and your response to Docetaxel Seacross. In particular,

please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles, fever and give her/him results of your blood tests. Such information will allow her/him to decide whether a dose reduction is needed. If you have any further questions on the use of this medicine, ask your doctor, or hospital pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Your doctor will discuss these with you and will explain the potential risks and benefits of your treatment.

The most commonly reported adverse reactions of Docetaxel Seacross alone are: decrease in the number of red blood cells or white blood cells, alopecia, nausea, vomiting, sores in the mouth, diarrhoea and tiredness.

The severity of adverse events of Docetaxel Seacross may be increased when Docetaxel Seacross is given in combination with other chemotherapeutic agents.

During the infusion at the hospital the following allergic reactions may occur (may affect more than 1 in 10 people):
• flushing, skin reactions, itching
• chest tightness; difficulty in breathing
• fever or chills
• back pain
• low blood pressure.

More severe reactions may occur.
If you had an allergic reaction to paclitaxel, you may also experience an allergic reaction to docetaxel, which may be more severe.

The hospital staff will monitor your condition closely during treatment. Tell them immediately if you notice any of these effects.

Between infusions of Docetaxel Seacross the following may occur, and the frequency may vary with the combinations of medicines that are received:

Very common (may affect more than 1 in 10 people):
• infections, decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection) and platelets
• fever: if this happens you must tell your doctor immediately
• allergic reactions as described above
• loss of appetite (anorexia)
• insomnia
• feeling of numbness or pins and needles or pain in the joints or muscles
• headache
• alteration in sense of taste
• inflammation of the eye or increased tearing of the eyes
• swelling caused by faulty lymphatic drainage
• shortness of breath
• nasal drainage; inflammation of the throat and nose; cough
• bleeding from the nose
• sores in the mouth
• stomach upsets including nausea, vomiting and diarrhoea, constipation
• abdominal pain
• indigestion

• hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed
• redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel (this may also occur on the arms, face, or body)
• change in the colour of your nails, which may detach
• muscle aches and pains; back pain or bone pain
• change or absence of menstrual period
• swelling of the hands, feet, legs
• tiredness; or flu-like symptoms
• weight gain or loss.
• infection of the upper respiratory tract.

Common (may affect up to 1 in 10 people):
• oral candidiasis
• dehydration
• dizziness
• hearing impaired
• decrease in blood pressure; irregular or rapid heart beat
• heart failure
• oesophagitis
• dry mouth
• difficulty or painful swallowing
• haemorrhage
• raised liver enzymes (hence the need for regular blood tests)
• rises in blood sugar levels (diabetes)
• decrease of the potassium, calcium and/or phosphate in your blood.

Uncommon (may affect up to 1 in 100 people):
• fainting
• at the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling
• blood clots.
• acute myeloid leukaemia and myelodysplastic syndrome (types of blood cancer) may occur in patients who are treated with docetaxel together with certain other anticancer treatments.

Rare (may affect up to 1 in 1,000 people):
• inflammation of the colon, small intestine, which could be fatal (frequency not known); intestinal perforation.

Frequency not known (cannot be estimated from the available data):
• interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing. Inflammation of the lungs can also develop when docetaxel therapy is used with radiotherapy)
• pneumonia (infection of the lungs)
• pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath)
• blurred vision due to swelling of the retina within the eye (cystoid macular oedema)
• decrease of the sodium and/or magnesium in your blood (electrolyte balance disorders)
• ventricular arrhythmia or ventricular tachycardia (manifested as irregular and/or rapid heartbeat, severe shortness of breath, dizziness, and/or fainting). Some of these symptoms can be serious. If this happens, you must tell your doctor immediately.
• injection site reactions at the site of a previous reaction.
• non-Hodgkin lymphoma (a cancer affecting the immune system) and other cancers may occur in patients who are treated with docetaxel together with certain other anticancer treatments.
• Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose,

genitals, hands or feet) with or without a rash. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscles.)
• acute Generalized Exanthematous Pustulosis (AGEP) (red, scaly widespread rash with bumps under the swollen skin (including your skin folds, trunk, and upper extremities) and blisters accompanied by fever.)
• tumour lysis syndrome is a serious condition revealed by changes in blood test such as increased level of uric acid, potassium, phosphorus and decreased level of calcium; and results in symptoms such as seizures, kidney failure (reduced amount or darkening of urine) and heart rhythm disturbance. If this happens, you must tell your doctor immediately.
• myositis (inflammation of the muscles -hot, red and swollen- which produces muscle pain and weakness)

Reporting of side effects
If you get any side effects talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOCETAXEL SEACROSS

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on outer carton and on the label of the vial after EXP. The expiry date refers to the last day of that month.

Do not store above 25ºC.
Store in the original package in order to protect from light.

Use the vial immediately after its opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

From a microbiological point of view, reconstitution/dilution must take place in controlled and aseptic conditions.

Use immediately the medicine once added into the infusion bag. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 8 hours in infusion bottle or 6 hours in infusion bag below 25°C including the one hour infusion.

Physical and chemical in-use stability of the infusion solution prepared as recommended has been demonstrated in non-PVC bags up to 48 hours when stored between 2 to 8°C.

Docetaxel infusion solution is supersaturated, therefore may crystallize over time. If crystals appear, the solution must no longer be used and shall be discarded.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Docetaxel Seacross contains

- The active substance is docetaxel.

  One ml docetaxel concentrate contains 20 mg docetaxel.

- The other ingredients are polysorbate 80, ethanol anhydrous (see section 2) and citric acid.

What Docetaxel Seacross looks like and contents of the pack

Docetaxel Seacross concentrate for solution for infusion is a clear viscous, colourless to brownish-yellow sterile solution.

The concentrate is supplied in a 2 ml colourless glass vial with a green flip-off closure. Each box contains one vial of 1 ml concentrate (20 mg docetaxel).

The concentrate is supplied in a 6 ml colourless glass vial with an orange flip-off closure. Each box contains one vial of 4 ml concentrate (80 mg docetaxel).

The concentrate is supplied in a 15 ml colourless glass vial with a red flip-off closure. Each box contains one vial of 8 ml concentrate (160 mg docetaxel).

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

[to be completed nationally]

This leaflet was last revised in 2023-07-13

The following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR USE WITH DOCETAXEL SEACROSS 20 mg/ml CONCENTRATE FOR SOLUTION FOR INFUSION

It is important that you read the entire contents of this guide prior to the preparation of the Docetaxel Seacross infusion solution.

RECOMMENDATIONS FOR THE SAFE HANDLING

Docetaxel Seacross is an antineoplastic agent and, as with other potentially toxic compounds, caution should be exercised when handling it and preparing its solutions. The use of gloves is recommended.

If Docetaxel Seacross concentrate or infusion solution should come into contact with skin, wash immediately and thoroughly with soap and water. If it should come into contact with mucous membranes, wash immediately and thoroughly with water.

PREPARATION OF THE INTRAVENOUS ADMINISTRATION

Preparation of the infusion solution

DO NOT use other docetaxel medicinal products consisting of 2 vials (concentrate and solvent) with this medicinal product (Docetaxel Seacross 20 mg/ml concentrate for solution for infusion, which contains only 1 vial).

Docetaxel Seacross 20 mg/ml concentrate for solution for infusion requires NO prior dilution with a solvent and is ready to add to the infusion solution.

- Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user. More than one vial of concentrate for solution for infusion may be necessary to obtain the required dose for the patient. For example, a dose of 140 mg docetaxel would require 7 ml docetaxel concentrate for solution.
- Aseptically withdraw the required amount of concentrate for solution for infusion with a calibrated syringe fitted with a 21G needle.

In Docetaxel Seacross 20 mg/ml vial the concentration of docetaxel is 20 mg/ml.

- Then, inject via a single injection (one shot) into a 250 ml infusion bag or bottle containing either 5% glucose solution or sodium chloride 9 mg/ml (0.9%) solution for infusion. If a dose greater than 190 mg of docetaxel is required, use a larger volume of the infusion vehicle so that a concentration of 0.74 mg/ml docetaxel is not exceeded.
- Mix the infusion bag or bottle manually using a rocking motion.
- From a microbiological point of view, reconstitution /dilution must take place in controlled and aseptic conditions and the infusion solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
  Once added as recommended into the infusion bag (PP) or infusion bottle (PE), the docetaxel infusion solution, if stored below 25°C, is stable for 8 hours in infusion bottle or for 6 hours in infusion bag. It should be used within 6-8 hours (including the one hour infusion IV administration).
  In addition, physical and chemical in-use stability of the infusion solution prepared as recommended has been demonstrated in non-PVC bags up to 48 hours when stored between 2°C to 8°C.
  Docetaxel infusion solution is supersaturated, therefore may crystallize over time. If crystals appear, the solution must no longer be used and shall be discarded.

- As with all parenteral products, infusion solution should be visually inspected prior to use, solutions containing a precipitate should be discarded.

DISPOSAL

All materials that have been utilised for dilution and administration should be disposed of according to standard procedures. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.