Package leaflet: Information for the patient

Resotere 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 or your pharmacist.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Resotere is and what it is used for

The name of this medicine is Resotere. 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.

Resotere 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, Resotere 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, Resotere could be administered in combination with doxorubicin and cyclophosphamide.
- For the treatment of lung cancer, Resotere could be administered either alone or in combination with cisplatin.
- For the treatment of prostate cancer, Resotere is administered in combination with prednisone or prednisolone.
- For the treatment of metastatic gastric cancer, Resotere is administered in combination with cisplatin and 5-fluorouracil.
- For the treatment of head and neck cancer, Resotere is administered in combination with cisplatin and 5-fluorouracil.

2. What you need to know before you use Resotere

You must not be given Resotere

- if you are allergic (hypersensitive) to docetaxel or any of the other ingredients of Resotere.
- if the number of white blood cells is too low.
- if you have a severe liver disease.

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

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

If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your doctor or pharmacist 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 Resotere 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 Resotere 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.

Resotere contains alcohol. Discuss with your doctor if you suffer from alcohol dependency or liver impairment. See also section "Resotere contains ethanol (alcohol)" below.

Other medicines and Resotere
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription. This is because Resotere or the other medicine may not work as well as expected and you may be more likely to get a side effect.

Pregnancy, breast-feeding and fertility

Ask your doctor for advice before being given any medicine.

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

You must not become pregnant during treatment with this medicine and must use an effective method of contraception during therapy, because Resotere 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 Resotere.

If you are a man being treated with Resotere, you are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because Resotere may alter male fertility.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Resotere contains ethanol (alcohol)
1 ml – vial:
This medicinal product contains 50 vol % ethanol (alcohol), i.e. up to 0.395 g (0.5 ml) per vial, equivalent to 10 ml of beer or 4 ml wine per vial.
4 ml – vial:

This medicinal product contains 50 vol % ethanol (alcohol), i.e. up to 1.58 g (2 ml) per vial, equivalent to 40 ml of beer or 16 ml wine per vial.
7 ml – vial:
This medicinal product contains 50 vol % ethanol (alcohol), i.e. up to 2.765 g (3.5 ml) per vial, equivalent to 70 ml of beer or 28 ml wine per vial.
8 ml – vial:
This medicinal product contains 50 vol % ethanol (alcohol), i.e. up to 3.16 g (4 ml) per vial, equivalent to 80 ml of beer or 33 ml wine per vial.

Harmful for those suffering from alcoholism.

To be taken into account if you are pregnant or if you are 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 alter the effects of other medicines.

The amount of alcohol in this medicine may impair your ability to drive or use machines.

3. How to use Resotere

Resotere 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
Resotere 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 Resotere. 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 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 Resotere 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 Resotere may be increased when Resotere is given in combination with other chemotherapeutic agents.

During the infusion at the hospital the following allergic reactions (may affect more than 1 in 10 people) may occur:

- flushing, skin reactions, itching,
- chest tightness; difficulty in breathing,
- fever or chills,
- back pain,
- low blood pressure.

More severe reactions may occur.

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

Between infusions of Resotere 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)
- 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 color 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

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)

Uncommon (may affect up to 1 in 100 people):
- fainting
- at the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling
- inflammation of the colon, small intestine; intestinal perforation
- blood clots.

Frequency unknown:
- 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 in your blood.

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist.This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system will be completed during the national phase]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Resotere

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the 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 25°C.

Store in the original package in order to protect from light.

Do not freeze.

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 Resotere contains

- The active substance is docetaxel. Each ml of concentrate for solution for infusion contains 20 mg docetaxel.
- The other ingredients are polysorbate 80, ethanol anhydrous and citric acid.

What Resotere looks like and contents of the pack
Resotere concentrate for solution for infusion is a yellow to brownish yellow clear oily solution.

Each box contains one vial of 1 ml concentrate (20 mg docetaxel).
Each box contains one vial of 4 ml concentrate (80 mg docetaxel).
Each box contains one vial of 7 ml concentrate (140 mg docetaxel).
Each box contains one vial of 8 ml concentrate (160 mg docetaxel).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in

The following information is intended for healthcare professionals only:

PREPARATION GUIDE FOR USE WITH RESOTERE 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION

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It is important that you read the entire contents of thisguide prior to the preparation of the Resotere infusion solution

Recommendations for the safe handling:
Docetaxel 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 Resotere 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

- **Resotere 20 mg/ml concentrate for solution for infusion, which contains only 1 vial with 1 ml (20 mg/1ml).**
- **Resotere 20 mg/ml concentrate for solution for infusion, which contains only 1 vial with 4 ml (80 mg/4ml).**
- **Resotere 20 mg/ml concentrate for solution for infusion, which contains only 1 vial with 7 ml (140 mg/7ml).**
- **Resotere 20 mg/ml concentrate for solution for infusion, which contains only 1 vial with 8 ml (160 mg/8ml).**

Resotere 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. From a microbiological point of view, the concentrate should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C.
Chemical and physical in-use stability of the open vial has been demonstrated for 4 weeks at 2 to 8°C.

- More than one vial of concentrate for solution for infusion may be necessary to obtain the required dose for the patient.
- Aseptically withdraw the required amount of concentrate for solution for infusion with a calibrated syringe fitted with a 21G needle.

In Resotere 20 mg/1 ml vial the concentration of docetaxel is 20 mg/ml.
In Resotere 80 mg/4 ml vial the concentration of docetaxel is 20 mg/ml.
In Resotere 140 mg/7 ml vial the concentration of docetaxel is 20 mg/ml.
In Resotere 160 mg/8 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, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions. Chemical and physical in-use stability has been demonstrated in polyolefin bags for 72 hours at 2 to 8°C and for 8 hours at 25°C. Although contact time is very little, only non-PVC tubing and administration sets are recommended for use as precaution.

Docetaxel solution for infusion 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.