

ONKOTRONE

Mitozantrone Concentrated Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ONKOTRONE.

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 ONKOTRONE 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 with the medicine. You may need to read it again.

What ONKOTRONE is used for

ONKOTRONE is used to treat various types of cancer. These include breast cancer, non-Hodgkin's lymphoma (a cancer of the lymph glands), and leukaemia.

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

ONKOTRONE works by stopping cancer cells from growing and multiplying.

Your doctor may have prescribed ONKOTRONE for another reason. Ask your doctor if you have any questions about why ONKOTRONE has been prescribed for you.

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

ONKOTRONE is not addictive.

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

Before you are given ONKOTRONE

When you must not be given it

Do not have ONKOTRONE if you have an allergy to ONKOTRONE or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to ONKOTRONE may 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 lightheadedness

Do not have ONKOTRONE if you have, or have had, any of the following medical conditions, unless you have first discussed this with your doctor:

- severe liver problems
- heart problems
- condition of the blood with a reduced number of red / white blood cells / platelets

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.

Do not have ONKOTRONE if you have already received the full, long-term dose of ONKOTRONE or another anthracycline medicine.

Examples of other anthracycline medicines are doxorubicin (also called Adriamycin or Caelyx), idarubicin (also called Zavedos), epirubicin and daunorubicin.

Do not have ONKOTRONE if you are pregnant or intend to become pregnant.

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

Both men and women taking ONKOTRONE and their partners must use a reliable method of contraception during and for 6 months after receiving ONKOTRONE.

Do not breastfeed while taking ONKOTRONE.

ONKOTRONE passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

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

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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

- liver problems
- kidney problems
- heart problems, including a heart attack
- gout, a disease with painful, swollen joints caused by high uric acid levels
- blood disorder with a reduced number of red / white blood cells / platelets
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)

Tell your doctor about any other medicines or treatments you are having, or have had in the past, for cancer, including radiation therapy.

If you have not told your doctor about any of the above, tell them before you start having ONKOTRONE.

Taking other medicines

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

Some medicines and ONKOTRONE may interfere with each other.

These medicines may be affected by ONKOTRONE, 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 and pharmacist may have more information on medicines to be careful with or avoid while having ONKOTRONE.

How ONKOTRONE is given

ONKOTRONE will always be given by specially trained doctors or nurses in a hospital or clinic.

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, kidney function and other chemotherapy medicines you are being given.

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

Several courses of ONKOTRONE 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 and any uncontrolled effects have been controlled.

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

How it is given

ONKOTRONE is given as an infusion (drip) into the veins. ONKOTRONE must only be given by a doctor or nurse.

How long it is given

ONKOTRONE is usually given every 21 days, but this can vary with the results of your blood tests. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Overdose

As ONKOTRONE 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 side effects after being given ONKOTRONE, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of an ONKOTRONE overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are using ONKOTRONE

Your urine may turn a blue-green colour for up to 24 hours after you have received ONKOTRONE. You may also notice a blue-green tinge in the whites of your eyes. These are normal effects of ONKOTRONE and will disappear after 1 or 2 days.

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may 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.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of ONKOTRONE at the appropriate times to get the best effects from your treatments.

Tell any other doctors, dentists, and pharmacists who are treating you that you are having ONKOTRONE.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having ONKOTRONE.

If you become pregnant while having ONKOTRONE, tell your doctor.

ONKOTRONE 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 immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or 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.

Tell the doctor or nurse immediately if you experience pain during the injection of ONKOTRONE.

Things you must not do

Do not have any immunizations (vaccinations) during treatment with ONKOTRONE or for some time after you have stopped treatment. If it is necessary for you to have a vaccination, discuss it with your doctor first.

Things to be careful of

Be careful driving or operating machinery until you know how ONKOTRONE affects you.

As with other medicines, ONKOTRONE may cause tiredness in some people. Make sure you know how you react to ONKOTRONE before you drive a car, operate machinery, or do anything else that could be dangerous. If you drink alcohol, tiredness may be worse.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having ONKOTRONE.

Like other medicines that treat cancer, ONKOTRONE may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Nausea
- Vomiting
- Mouth ulcers
- Unusual hair loss or thinning
- Blue-green colouration of urine, or the whites of the eyes
- Diarrhoea
- Decreased appetite
- Constipation
- Stomach pain
- Altered sense of taste
- Darkening of nails
- Rash

These are the more common side effects of ONKOTRONE.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- tiredness, headaches, short of breath when exercising, dizziness & looking pale

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:

- bleeding or bruising more easily than normal, nosebleeds
- difficulty in breathing
- fever or chills
- heart disease: symptoms include fatigue, chest pain, palpitations, altered heart beat
- blood in urine or stools
- pain near the injection site

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

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

After using ONKOTRONE

Storage

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

Product description

What it looks like

ONKOTRONE is a blue liquid in a sealed glass vial. It is mixed with another liquid before use. Each vial is used only once and any left over material is discarded.

Ingredients

Active ingredient:

- mitozantrone (as hydrochloride)

Other ingredients:

- sodium chloride
- sodium acetate
- acetic acid
- water for injection

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

ONKOTRONE is available in the following sizes:

20mg/10mL AUST R: 75723

25mg/12.5mL AUST R: 75724

Sponsor

Baxter Healthcare Pty Limited
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