

ONKOTRONE

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 receiving ONKOTRONE?

ONKOTRONE contains the active ingredient mitozantrone hydrochloride. ONKOTRONE is used to treat various types of cancer. For more information, see Section [1. Why am I receiving ONKOTRONE?](#) in the full CMI.

2. What should I know before receiving ONKOTRONE?

Do not use if you have ever had an allergic reaction to ONKOTRONE (mitozantrone hydrochloride) 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 receiving ONKOTRONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONKOTRONE 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 is ONKOTRONE given?

- Your doctor or trained nurse will give ONKOTRONE by an infusion (drip) into a vein (intravenously). The infusion usually takes 15 to 30 minutes. You may need several infusions at regular intervals. These are known as 'cycles of chemotherapy'.

More instructions can be found in Section [4. How is ONKOTRONE given?](#) in the full CMI.

5. What should I know while receiving ONKOTRONE?

Things you should do	<ul style="list-style-type: none">Be aware that your urine may turn a blue-green colour after your dose of ONKOTRONEKeep all your doctor's appointments to get the best effects from treatment, and so your progress can be checked.For men and women of childbearing age: Use a reliable form of birth control while you are being treated with ONKOTRONE and for at least 6 months after your treatment has stopped.Call your doctor straight away if you become pregnant while you are receiving ONKOTRONE or if you experience any pain during the injection of ONKOTRONERemind any doctor, dentist, nurse or pharmacist you visit that you are receiving ONKOTRONE.Take precautions to minimise the risk of infections and bleeding.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how ONKOTRONE affects you.
Drinking alcohol	<ul style="list-style-type: none">Avoid drinking alcohol while you are receiving ONKOTRONE.

For more information, see Section [5. What should I know while receiving ONKOTRONE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. You may experience non-serious and serious side effects, including cardiac failure, while on ONKOTRONE. Most common side effects include nausea, vomiting, painful mouth ulcers, difficulty swallowing, fatigue, pale skin, bruising, fever, tiny red, purple or brown spots on skin, hair loss and blue-green urine.

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.

Speak to your doctor, nurse or pharmacist if you experience any symptoms.

ONKOTRONE

Active ingredient: *mitozantrone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONKOTRONE. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using ONKOTRONE.**

Where to find information in this leaflet:

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

1. Why am I receiving ONKOTRONE?

ONKOTRONE contains the active ingredient mitozantrone hydrochloride. ONKOTRONE is a type of chemotherapy medicine. It belongs to a group of medicines called antineoplastic or cytotoxic medicines.

ONKOTRONE is used to treat various types of cancer, including:

- breast cancer
- non-Hodgkin's lymphoma (a cancer of the lymph glands)
- adult acute non-lymphocytic leukaemia (ANLL)
- advanced chronic myeloid leukaemia (CML)

ONKOTRONE works by stopping cancer cells from growing and multiplying. It may be used in combination with other medicines to treat cancer.

2. What should I know before I receive ONKOTRONE?

Warnings

Do not have ONKOTRONE if:

- you are allergic to mitozantrone hydrochloride, the active ingredient in ONKOTRONE, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have the following medical conditions (unless you have first discussed these with your doctor):
 - severe liver problems
 - a condition of the blood with a reduced number of red or white blood cells or platelets because of previous chemotherapy or radiotherapy.

- You have already received a long-term dose of ONKOTRONE or similar medicines such as doxorubicin, idarubicin, epirubicin, or daunorubicin, and you have heart problems
- you are pregnant or breastfeeding (see '**Pregnancy and breastfeeding**')
- you are planning to become pregnant (see '**People of childbearing age**')

Check with your doctor if you:

- have any other medical conditions, including:
 - liver problems
 - kidney problems
 - heart problems, including a heart attack
 - gout, a disease with painful, swollen joints caused by high uric acid levels
 - a blood disorder with a reduced number of red or white blood cells or platelets
 - lowered immunity due to treatment with certain medicines (corticosteroids, cyclosporine, medicines used to treat cancer) or radiation treatment
- take any medicines for any other conditions
- in the past, have taken medicines for cancer, or had radiation therapy.
- have had a recent infection

If you have an infection, your doctor may decide to delay your treatment until your infection is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

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

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 in pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant, to discuss the risks and benefits. See also '**People of childbearing age**'.

Do not breastfeed while receiving ONKOTRONE.

ONKOTRONE passes into the breast milk and may affect the breast-fed baby.

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

People of childbearing age

Use a reliable form of birth control while you are being treated with ONKOTRONE and for at least 6 months after your treatment has stopped.

ONKOTRONE may cause birth defects if either males or females are being treated with it at the time of conception.

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 ONKOTRONE may interfere with each other. These medicines may be affected by ONKOTRONE or may affect how it works.

- doxorubicin, idarubicin, epirubicin, or daunorubicin also known as ‘anthracyclines’
- other chemotherapy medicines including cyclophosphamide, fluorouracil, vincristine, vinblastine, bleomycin, methotrexate, and cytosine arabinoside
- cyclosporine, a medicine used in organ transplants
- vaccines, especially live vaccines

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

4. How is ONKOTRONE given?

How it is given

- Your doctor or trained nurse will give ONKOTRONE by an infusion (drip) into a vein (intravenously).
- Your dose is usually given over 15 to 30 minutes.
- Doses are usually repeated every 21 days, in what is called a cycle of chemotherapy. Intervals may vary, depending on your blood test results.
- Several cycles may be needed depending on your response to treatment. Your doctor will advise how many cycles you will need.
- ONKOTRONE may be given alone or in combination with other cancer-treating medicines.

How much is given

- Your doctor will decide how much ONKOTRONE to give you.
- The amount depends on your condition, and on factors such as your weight and other chemotherapy medicines you are receiving.
- Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects are managed.

If you receive too much ONKOTRONE

The doctor or nurse giving you ONKOTRONE is highly trained and qualified, so it is unlikely that you will be given an overdose.

If you think that you have used too much ONKOTRONE, you may need urgent medical attention.

You should immediately:

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

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving ONKOTRONE?

Things you should do

- Be aware that your urine may turn a blue-green colour after your dose of 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.

- Keep all your doctor’s appointments to get the best effects from treatment, and so your progress can be checked.

It is important to have your follow-up doses at the appropriate times to get the best treatment outcomes.

Your doctor may also want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.

- Remind any doctor, dentist, nurse or pharmacist you visit that you are using ONKOTRONE.
- For men and women of childbearing age: Use a reliable form of birth control while you are being treated with ONKOTRONE and for at least 6 months after your treatment has stopped.

ONKOTRONE may cause birth defects if either males or females are being treated with it at the time of conception.

Tell your doctor straight away if you:

- become pregnant while receiving ONKOTRONE.
- experience any pain during the injection of ONKOTRONE

Reducing the risk of infection and bleeding

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.

To reduce the risk of infection and bleeding, follow these precautions:

- 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.

Driving or using machines

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

As with many other medicines, ONKOTRONE may cause tiredness in some people.

Drinking alcohol

Avoid drinking alcohol while you are on ONKOTRONE. Alcohol may worsen some side effects of ONKOTRONE, such as tiredness.

Looking after your medicine

ONKOTRONE will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place, where the temperature stays below 25°C, and is protected from light. It will not be frozen.

Getting rid of any unwanted medicine

ONKOTRONE is for single use, and for one person only. Your doctor or nurse will discard any unused medicine. They will not save unused portions for later, either for you or anyone else.

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.

Less serious side effects

Less serious side effects	What to do
<p>Gut related:</p> <ul style="list-style-type: none"> • nausea • vomiting • mouth ulcers • diarrhoea • decreased appetite • constipation • stomach pain • altered sense of taste <p>Hair and skin:</p> <ul style="list-style-type: none"> • unusual hair loss or thinning • darkening of nails or skin (pigmentation) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • rash <p>Others:</p> <ul style="list-style-type: none"> • blue-green colouration of urine, or the whites of the eyes • weakness or sleepiness • feeling anxious • changes in sensation (numbness or tingling in any part of your body) • no menstrual bleeding 	
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Serious side effects

Serious side effects	What to do
<p>Blood count related:</p> <ul style="list-style-type: none"> • tiredness, headaches, short of breath when exercising, dizziness & looking pale • bleeding or bruising more easily than normal, nosebleeds <p>Infection-related</p> <ul style="list-style-type: none"> • signs of sepsis (an extreme immune response to infection) which may include: <ul style="list-style-type: none"> • fever or chills • confusion • difficulty breathing • convulsions <p>Heart or lung related:</p> <ul style="list-style-type: none"> • fatigue • chest pain • palpitations • altered heartbeat • difficulty in breathing • dry cough • swelling and weight gain from fluid in your ankles, lower legs, or belly <p>Injection related:</p> <ul style="list-style-type: none"> • pain, redness, swelling, burning near the injection site or along the infusion vein • blue colour of skin near the injection site <p>Allergic reaction related:</p> <ul style="list-style-type: none"> • 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 light-headedness <p>Others:</p> <ul style="list-style-type: none"> • blood in urine or stools 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • severe stomach pain or swelling • yellowing of the whites of the eyes, and yellowing of the skin 	
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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.

In some cases, patients have developed other cancers, several years after treatment with ONKOTRONE.

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

Other side effects not listed here may occur in some people. Some side effects can only be detected by your doctor by physical examination, laboratory tests or scans.

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.

What ONKOTRONE contains

Active ingredient (main ingredient)	mitozantrone hydrochloride
Other ingredients (inactive ingredients)	sodium chloride, sodium acetate, glacial acetic acid and water for injections

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

What ONKOTRONE looks like

ONKOTRONE is a clear dark blue concentrated injection. It is mixed with a liquid before use. It is available in the following sizes:

- 10mg/5mL – Aust R 75722
- 20mg/10mL – Aust R 75723
- 25mg/12.5mL – Aust R 75724
- 30mg/15mL – Aust R 75725

Not all sizes may be marketed.

Who distributes ONKOTRONE

Baxter Healthcare Pty Ltd
 1 Baxter Drive
 Old Toongabbie
 NSW 2146
 Australia

ONKOTRONE is a trademark of Baxter Healthcare S.A.

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