

Doxorubicin Ebewe

Doxorubicin hydrochloride Injection
(*Dox-oh-roo-bi-sin*)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Doxorubicin Ebewe Injection. 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 or pharmacist has weighed the risks of you taking Doxorubicin Ebewe injection against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Your doctor or pharmacist can provide you with more information about Doxorubicin Ebewe.

Keep this leaflet with the medicine. You may need to read it again.

What Doxorubicin Ebewe injection is used for

Doxorubicin Ebewe Injection is used to treat certain cancers. Doxorubicin Ebewe belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. Doxorubicin Ebewe is thought to work by killing cancer cells, and stopping cancer cells from growing and multiplying. Your doctor may have prescribed Doxorubicin Ebewe injection for another reason. Ask your doctor if you have any questions about why Doxorubicin Ebewe injection has been prescribed for you.

Doxorubicin Ebewe is not addictive.

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

Before you are given Doxorubicin Ebewe injection

When you must not be given it

You must not be given Doxorubicin Ebewe if you have an allergy to Doxorubicin or any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to Doxorubicin Ebewe Injection 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.

- **You must not be given Doxorubicin Ebewe if you have very low white blood cell counts.**
- **You must not be given Doxorubicin Ebewe if you have a very inflamed and sore mouth.**
- **You must not be given Doxorubicin Ebewe if you have an infection.**
- **You must not be given Doxorubicin Ebewe if you have heart problems.**
- **You must not be given Doxorubicin Ebewe if you have already received the full long-term dose of Doxorubicin Ebewe, or other anthracyclines such as daunorubicin or epirubicin.**
- **You must not be given Doxorubicin Ebewe if you are pregnant or intend to become pregnant. Doxorubicin Ebewe may affect your developing baby if you are given it during pregnancy.**

It is recommended that you and your doctor discuss the need for Doxorubicin Ebewe treatment during pregnancy, and the possible risks and benefits of using Doxorubicin Ebewe during pregnancy.

Doxorubicin Ebewe may cause birth defects if either the male or the female is undergoing treatment at the time of conception, or if the female is receiving Doxorubicin Ebewe during early pregnancy. It is best to use some kind of birth control while you are receiving Doxorubicin Ebewe, and for at least 12 weeks after you stop receiving it. Your doctor will discuss this with you.

Many cancer medicines can cause infertility. Your doctor should discuss this issue with you before you begin therapy with Doxorubicin Ebewe.

You should not be given Doxorubicin Ebewe if you are breast-feeding or plan to breast-feed. Doxorubicin Ebewe passes into breast milk. As Doxorubicin Ebewe may cause serious side effects in a breast-fed baby, breast-feeding is not recommended while you are receiving it.

If you are not sure whether you should be given Doxorubicin Ebewe, 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 or pharmacist if you have or have had any medical conditions, especially the following:

- heart problems
- liver problems
- a condition of the blood with a reduced number of red or white blood cells or platelets
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer including radiation therapy
- lowered immunity due to diseases including HIV/AIDS.

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 use Doxorubicin Ebewe if you have already received the full, long-term dose of Doxorubicin Ebewe or another anthracycline medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Doxorubicin Ebewe.

Taking other medicines

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

Some medicines and Doxorubicin Ebewe may interfere with each other. These include:

- other medicines used to treat cancer, radiation therapy, or any other treatment which lowers your immune system
- some medicines used to treat high blood pressure and angina eg. propranolol, calcium channel blockers
- medicines for gout eg allopurinol, colchicine, probenecid
- phenobarbitone or phenytoin, medicines used for epilepsy
- some medicines used to treat infections eg. clindamycin, lincamycin
- vaccines (ask your doctor).

These medicines may be affected by Doxorubicin Ebewe, or may affect how well it works. You may need different amounts of your medicine, or you may need to take 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 you are being given Doxorubicin Ebewe. You should not be given any vaccinations (immunisations) without your doctor's approval while you are being treated with Doxorubicin Ebewe, and for up to 12 months after you stop treatment with it. Doxorubicin Ebewe may lower your body's resistance to infection and there is a chance that you may get the infection the immunisation is meant to prevent.

In addition, other people living in your household should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

How Doxorubicin Ebewe injection is given

How much is given

Your doctor will decide what dose will receive. This depends on your condition and other factors, such as your weight and other chemotherapy medicines you are being given. Ask your doctor if you want to know more about the dose of Doxorubicin Ebewe you receive.

How it is given

Doxorubicin Ebewe is usually given as a slow injection into a vein. It is sometimes injected through a rubber tube (called a catheter) into your bladder. Doxorubicin Ebewe may be given alone or in combination with other drugs. Several courses of Doxorubicin Ebewe 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 unwanted effects have been controlled. Doxorubicin Ebewe Injection must only be given by a doctor or nurse.

How long is it given

Doxorubicin Ebewe is usually given either once every 21 days, or for three consecutive days and repeated every 3 to 4 weeks. These are called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Overdose

As Doxorubicin Ebewe is most likely to be given to you in hospital 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 Doxorubicin Ebewe, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

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

While you are being given Doxorubicin Ebewe injection

Things you must do

Be sure to keep all of 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 follow up cycles of Doxorubicin Ebewe at the appropriate times to get the best effects from your treatment.

Doxorubicin Ebewe can temporarily lower the number of white blood cells in your blood, increasing the chance of you getting an infection. It can also lower the number of platelets, which are necessary for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

If you can, avoid people with infections. Check with your doctor immediately if you think you are getting an infection, or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

Check with your doctor immediately if you notice any unusual bleeding or bruising, black stools, blood in urine or stools or pinpoint red spots on your skin.

Be careful when using a toothbrush, dental floss or toothpick. Your doctor or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done.

Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.

Be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters.

Avoid contact sports or other situations where bruising or injury could occur.

Doxorubicin Ebewe and its 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 chemotherapy and for one week after the treatment period:

Flush the toilet twice to dispose of any body fluids and waste.

Wear 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.

Wash 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.

Place 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.

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of Doxorubicin Ebewe.

Tell your doctor or nurse immediately if you feel any pain, burning or stinging at the site of injection.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given Doxorubicin Ebewe.

If you are about to start on any new medicine, tell your doctor, dentist or pharmacist that you are being given Doxorubicin Ebewe.

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

If you plan to be vaccinated within a year of being given Doxorubicin Ebewe, tell the doctor before you are vaccinated.

If you become pregnant while or soon after being given Doxorubicin Ebewe, tell your doctor or pharmacist immediately.

Things to be careful of

Be careful to use an effective method of contraception while you are using Doxorubicin Ebewe. Your doctor will tell you when it is safe to stop using contraception.

Be careful driving or operating machinery until you know how Doxorubicin Ebewe affects you. This medicine may cause dizziness or light-headedness in some people. If you have these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Doxorubicin Ebewe or after the injection.

Doxorubicin Ebewe helps most people with certain cancers, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

- inflammation, swelling, blistering or soreness at the injection site
- hair loss
- nausea and vomiting
- burning in the mouth, throat, vagina or rectum
- diarrhoea
- dehydration
- facial flushing
- bruising
- red coloured urine.

These are the more common side effects of Doxorubicin Ebewe. Tell your doctor or nurse as soon as possible if you notice any of the following:

- hives
- discolouration of nail beds and skin creases
- skin rash
- drowsiness
- conjunctivitis
- excessive tears
- the return of skin reactions in areas where you may have had radiation treatment previously
- poor appetite.

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 the Accident and Emergency department of your nearest hospital:

- bloody or dark stools
- chills, fever or symptoms of an infection
- irregular heart beat.

These are very serious side effects. You may need urgent medical attention or hospitalisation. If the Doxorubicin Ebewe is being injected into the bladder, tell the doctor or pharmacist if you notice any of the following:

- stomach pain
- blood in the urine
- pain on passing urine
- frequent urination

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.

Treatment with Doxorubicin Ebewe may cause changes in your blood cells which may be serious. Doxorubicin Ebewe may also affect how well your heart works. Your doctor will arrange regular blood tests and checks to detect any changes.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

After being given Doxorubicin Ebewe injection

Storage

Doxorubicin Ebewe Injection will be stored in the pharmacy or on the ward. The injection is kept in a refrigerator, where the temperature stays between 2 and 8°C. After use, any unused portion of the injection will be discarded.

Product Description

What it looks like

Doxorubicin Ebewe injection is a clear red liquid in a vial.

Doxorubicin Ebewe comes in the following strengths;

- Doxorubicin Ebewe injection 10mg in 5ml, packs of 1
- Doxorubicin Ebewe injection 50mg in 25ml, packs of 1

Ingredients

Active ingredient:

Doxorubicin hydrochloride

Other ingredients:

sodium chloride

water

Doxorubicin Ebewe Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Doxorubicin Ebewe is made by
EBEWE Pharma Ges.m.b.H. Nfg. KG
A-4866 Unterach
Austria

Sponsor

Doxorubicin Ebewe is distributed in Australia by:
Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Australia
Tel: 1800 726 369

Doxorubicin Ebewe is distributed in New Zealand by:
Novartis New Zealand Ltd
PO Box 99102
Newmarket, Auckland 1149
New Zealand
Tel: 0800 354 335

10mg in 5mL AUST R 118528
50mg in 25mL AUST R 118529
100mg in 50mL AUST R 118530 (Pharmacy Bulk Pack, for hospital use only)
200mg in 100mL AUST R 118531 (Pharmacy Bulk Pack for hospital use only)

This leaflet was prepared on 21 August 2019.