

DOXORUBICIN ACCORD

Doxorubicin hydrochloride Concentrated Injection 10 mg/5 mL and 200 mg/100 mL

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before treatment with Doxorubicin Accord.

This leaflet answers some common questions about this medicine.

It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Doxorubicin Accord against the benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Please keep this leaflet.

You may need to read it again.

What Doxorubicin Accord is used for

Doxorubicin Accord is used to treat many types of cancer. Doxorubicin Accord works by stopping cancer cells from growing and multiplying. It contains the active ingredient doxorubicin hydrochloride.

Ask your doctor if you have any questions about why Doxorubicin Accord has been prescribed for you.

Doxorubicin Accord is to be given only under the strict supervision of your doctor.

Doxorubicin Accord is not addictive.

Before you are given it

When you must not be given Doxorubicin Accord

Do not have Doxorubicin Accord if you are allergic to Doxorubicin Accord or have had an allergic reaction to any other cancer medication e.g. daunorubicin, epirubicin, mitozantrone.

Symptoms of an allergic reaction to Doxorubicin Accord 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
- light-headedness or back pain.

Do not have Doxorubicin Accord if:

- you have bone marrow suppression (reduced number of red or white blood cells or platelets) caused by previous treatment with other cancer medicines or radiation therapy, symptoms include tiredness, mouth ulcers or bleeding or bruising more easily than usual
- you have a generalised infection
- you have an irregular heart rate, poor blood flow to the heart or had a heart attack
- you have severe liver problems
- you have previously received treatment with the maximum dose of medicines such as doxorubicin (Doxorubicin Accord), daunorubicin, epirubicin, idarubicin, mitozantrone or mitomycin C
- you are pregnant or likely to become pregnant, as it may harm your developing baby

- you are breastfeeding, as it passes into breast milk and may affect your child.

Do not have the infusion into the bladder if you have:

- a tumour of the bladder wall
- a urinary infection
- bladder inflammation
- a catheter in the bladder
- blood in your urine.

Before you are given it

Tell your doctor if you have any heart or liver problems.

You will be given a blood test and your heart will be monitored before you start treatment with Doxorubicin Accord.

Taking other medicines

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

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

- other cancer medicines, such as cyclophosphamide, paclitaxel, 6-mercaptopurine, sorafenib
- some medicines used to prevent blood clots, such as heparin
- propranolol and other medicines for your heart.
- inactivated vaccines
- verapamil used for high blood pressure, angina or irregular heart beat
- phenobarbitone and phenytoin used to treat epilepsy
- St. John's Wort, a herbal supplement, used for mild anxiety and low mood
- cyclosporin used in transplant patients to prevent organ rejection

These medicines may be affected by Doxorubicin Accord, 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 will advise you.

Doxorubicin Accord given at the same time as radiation therapy may also cause unwanted effects.

Your doctor has more information on medicines to be careful with or avoid while using Doxorubicin Accord.

How is it given

You should only be treated with Doxorubicin Accord by a doctor who is experienced in treating patients with cancer. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled health care professionals.

You will be given a blood test and your heart will be monitored before you start treatment with Doxorubicin Accord.

Doxorubicin Accord is given by slow infusion into a vein or the bladder. If it is infused into the bladder, you will be asked not to urinate for one hour while Doxorubicin Accord is given.

Tell your doctor or nurse immediately if stinging, burning or pain develops at the injection site.

Treatment is usually given once every 3 weeks, or on three successive days repeated every 4 weeks.

However, your doctor may give Doxorubicin Accord more or less frequently.

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, liver function and the effect on your bone marrow of any previous treatment you may have had with x-ray or chemotherapy medicines.

Ask your doctor if you have any questions about the dose of Doxorubicin Accord and how it is given.

If you are given too much (overdose)

As Doxorubicin Accord is likely to be given to you in hospital under the supervision of a doctor, it is unlikely that you will receive too much.

However, immediately tell your doctor or telephone the Poisons Information Centre 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital if you have side effects after being given Doxorubicin Accord.

You may need urgent medical attention.

Symptoms of overdose with Doxorubicin Accord include the side effects below in the 'Side Effects' section, but they might be more severe.

While you are being given it

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having or have had treatment with Doxorubicin Accord.

Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with Doxorubicin Accord.

It is also important to inform your doctor if you have any infection or fever before, during or after treatment with Doxorubicin Accord, as it will lower your ability to fight infection.

Tell your doctor or nurse immediately if stinging, burning or pain develops at the injection site.

Doxorubicin Accord is known to be very powerful at lowering 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.

Take the following precautions 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.
- Avoid vaccination with certain vaccines. Your doctor or pharmacist will tell you what vaccines to avoid.

Your doctor will monitor the effects of Doxorubicin Accord on your blood, liver and heart regularly by giving you tests.

Men and women should use a reliable method of contraception (birth control).

If you become pregnant while on treatment with Doxorubicin Accord, consult your doctor.

Things to be careful of

Special care should be taken if it is necessary that you drive or operate machinery while undergoing treatment with Doxorubicin Accord, especially if you are in a weakened condition.

Side Effects

Tell your doctor as soon as possible if you do not feel well during or after treatment with Doxorubicin Accord.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

- nausea and vomiting. This may be expected 3-6 hours after Doxorubicin Accord is given and may last for several hours
- diarrhoea, dehydration, flushing of the face, abdominal pain
- loss of appetite may be expected for 24 hours following each treatment with Doxorubicin Accord. This may occasionally last for several days
- Doxorubicin Accord may colour your urine red for 1-2 days after treatment. This is no cause for alarm
- a burning sensation in the mouth, throat, food pipe, rectum or vagina may occur usually 5 to 10 days after treatment with Doxorubicin Accord. This pain will normally subside within 10 days
- hair loss is expected 1 to 2 weeks after beginning treatment with Doxorubicin Accord. You may lose all your hair, but after treatment is stopped, your hair is expected to grow back. Male patients may notice lack of beard growth during treatment
- skin infections, blisters, itchy skin
- bleeding or easy bruising
- permanent darkening of areas on the skin, nail beds, and the inside of the mouth
- discharge with itching of the eyes and crusty eyelids, dry eyes
- excess tears
- redness or pins and needles on the palms of your hands and soles of your feet
- drowsiness, unusual tiredness, weakness, feeling unwell, hot flushes, shock
- painful swelling of joints (gout)
- weight gain.

- infertility in both men and women
- Women may stop menstruating. Regular menstruation usually returns a few months after treatment is stopped in premenopausal women, although premature menopause can occur.
- Men may permanently experience a low sperm count or remain infertile. Sometimes male fertility may return several years after stopping Doxorubicin Accord therapy.

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

- swelling and redness of skin along the vein in which Doxorubicin Accord is injected
- infections, fever, sweats, severe chills, bruising more easily than normal
- fatigue, chest pain, palpitations, shortness of breath or swelling in the feet or legs due to fluid build-up. Doxorubicin Accord may also affect heart muscle and function. Your doctor will monitor your heart regularly before, during and after treatment.
- bleeding or ulceration of the bowel
- blood poisoning
- kidney problems
- blockage of a blood vessel caused by a clot
- leukaemia.

Other side effects not listed above may occur in some patients.

If you are given Doxorubicin Accord into the bladder, tell your doctor as soon as possible if you develop the following temporary side effects:

- cystitis (pain in the bladder or back, blood in urine)
- difficulty passing urine or an increased frequency of passing urine.

Tell your doctor if you notice anything that is making you feel unwell.

Storage

This medicine will be stored in the hospital pharmacy. Vials of Doxorubicin Accord Injection should be kept in a refrigerator (2°C to 8°C). Do not freeze. Protect from light.

Product Description

What it looks like

Doxorubicin Accord injection is a clear red solution in a glass vial

Ingredients

Active ingredient:

Doxorubicin Accord

Inactive ingredients:

Sodium chloride

Water for injections.

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

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

Australian Register numbers

10 mg/5 mL: AUST R 174249

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