

ACCORD DOXORUBICIN

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

Consumer Medicine Information

Version 11

What is in this leaflet

Please read this leaflet carefully before treatment with ACCORD DOXORUBICIN

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 ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN is used for

ACCORD DOXORUBICIN is used to treat certain cancers.

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

ACCORD DOXORUBICIN is thought to work by killing cancer cells, and stopping cancer cells from growing and multiplying. It contains the active ingredient doxorubicin hydrochloride.

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

ACCORD DOXORUBICIN is not addictive. This medicine is available only with a doctor's prescription.

ACCORD DOXORUBICIN is to be given only under the strict supervision of your doctor.

Before you are given ACCORD DOXORUBICIN

When you must not be given it

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

Symptoms of an allergic reaction to ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN if you have any of the following:

- very low white blood cell counts.
- a very inflamed and sore mouth.
- an infection.
- heart problems
- severe liver problems.

You must not be given ACCORD DOXORUBICIN into the bladder if you have any of the following

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

You must not be given ACCORD DOXORUBICIN if you have already received the full long-term dose of doxorubicin, or other anthracyclines such as daunorubicin or epirubicin.

You must not be given ACCORD DOXORUBICIN if you are pregnant or intend to become pregnant.

ACCORD DOXORUBICIN may affect your developing baby if you are given it during pregnancy.

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

ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN during early pregnancy. It is best to use some kind of birth control while you are receiving ACCORD DOXORUBICIN, 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 ACCORD DOXORUBICIN.

You should not be given ACCORD DOXORUBICIN if you are breastfeeding or plan to breast-feed.

Doxorubicin passes into breast milk. As ACCORD DOXORUBICIN may cause serious side effects in a breastfed baby, breast-feeding is not recommended while you are receiving it.

If you are not sure whether you should be given ACCORD DOXORUBICIN, 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.

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

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 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)
- medicines used for epilepsy (phenobarbitone or phenytoin)
- some medicines used to treat infections (eg. clindamycin, lincamycin)
- vaccines (ask your doctor)
- cyclosporine, an immunosuppressant medicine
- medicines such as methotrexate and streptozocin which may impair liver function

These medicines may be affected by doxorubicin, 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 ACCORD DOXORUBICIN.

You should not be given any vaccinations (immunisations) without your doctor's approval while you are being treated with ACCORD DOXORUBICIN, and for up to 12 months after you stop treatment with it.

ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN you receive.

How it is given

ACCORD DOXORUBICIN is usually given as a slow injection into a vein. It is sometimes injected through a rubber tube (called a catheter) into your bladder.

ACCORD DOXORUBICIN may be given alone or in combination with other medicines.

Several courses of ACCORD DOXORUBICIN 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.

ACCORD DOXORUBICIN
Injection must only be given by a doctor or nurse.

How long is it given

ACCORD DOXORUBICIN 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.

If you are given too much (overdose)

As ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26)

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

While you are given it

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 ACCORD DOXORUBICIN at the appropriate times to get the best effects from your treatment.

ACCORD DOXORUBICIN 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.

ACCORD DOXORUBICIN 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 nonbleaching 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 ACCORD DOXORUBICIN. 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 ACCORD DOXORUBICIN.

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

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

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

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

Things to be careful of

Be careful to use an effective method of contraception while you are using ACCORD DOXORUBICIN.

Your doctor will tell you when it is safe to stop using contraception.

Side effects

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

ACCORD DOXORUBICIN 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.

Infertility can occur in patients given ACCORD DOXORUBICIN. Women may also stop menstruating. Regular menstruation usually returns after termination of therapy, although premature menopause can occur.

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
- abdominal pain
- bruising
- red coloured urine.

These are the more common side effects of ACCORD DOXORUBICIN.

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

- hives or skin rash
- discolouration of nail beds and skin creases
- drowsiness
- hot flushes
- shock
- 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 ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN may cause changes in your blood cells which may be serious. ACCORD DOXORUBICIN 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 ACCORD DOXORUBICIN may take some time to occur. Therefore, even after you have finished your ACCORD DOXORUBICIN treatment, you should tell your doctor immediately if you notice any of the side effects listed in this section.

After taking ACCORD DOXORUBICIN

Storage

Store at 2°C to 8°C (Refrigerate. Do not freeze.) Protect from light.

After use, any residue should be discarded within 24 hours of opening.

Product description

What it looks like

ACCORD DOXORUBICIN injection is a clear red solution in a glass vial. It is available in 2 sizes: 10 mg/5 mL and 200 mg/100 mL.

- The 5 mL vial is supplied as single dose vials. The single dose vials should be used in one patient on one occasion only and any residue should be discarded within 24 hours of opening.
- The 100 mL vial is supplied as pharmacy bulk pack for hospital use only. The 100 mL vial is for use on one occasion for multi-dose dispensing and any residue should be discarded within 24 hours of opening.

Ingredients

Active ingredient:

- Doxorubicin hydrochloride

Other ingredients:

- Sodium chloride
- Water for injections

It might also contain hydrochloric acid

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

Name and Address of the Sponsor

Accord Healthcare Pty Ltd.

Unit 702/23, Queens Road,
Melbourne, Victoria, 3004
Australia

Australian Registration Numbers

- 10 mg/5 mL: AUST R 174247
- 200 mg/100 mL: AUST R 174244

Date of Approval

TGA approval: 29th September 2011

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