

ADRIAMYCIN®

Doxorubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before treatment with ADRIAMYCIN.

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 ADRIAMYCIN 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 ADRIAMYCIN is used for

ADRIAMYCIN is used to treat many types of cancer.

ADRIAMYCIN 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 ADRIAMYCIN has been prescribed for you.

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

ADRIAMYCIN is not addictive.

Before you are given it

When you must not be given ADRIAMYCIN

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

Symptoms of an allergic reaction to ADRIAMYCIN 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 ADRIAMYCIN 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 (ADRIAMYCIN), daunorubicin, epirubicin, idarubicin, mitozantrone or mitomycin C
- you are advised to avoid pregnancy during treatment as it may harm your developing baby
- you are breastfeeding, as it passes into breast milk and may affect your child. Women should not breastfeed while undergoing treatment and for at least 10 days after the last dose of Adriamycin. Consult your doctor or midwife if you have any concerns about being unable to breastfeed for this period.

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 start ADRIAMYCIN

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 ADRIAMYCIN.

You are advised to seek doctor consultation on fertility preservation before treatment with Adriamycin

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 ADRIAMYCIN 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 ADRIAMYCIN, 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.

ADRIAMYCIN 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 ADRIAMYCIN.

How ADRIAMYCIN is given

You should only be treated with ADRIAMYCIN 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 ADRIAMYCIN.

ADRIAMYCIN 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 ADRIAMYCIN 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 ADRIAMYCIN 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 ADRIAMYCIN and how it is given.

If you are given too much (overdose)

As ADRIAMYCIN 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 (Phone Australia 13 11 26) for advice, or go to Accident and Emergency at your nearest

hospital if you have side effects after being given ADRIAMYCIN.

You may need urgent medical attention.

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

While you are 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 ADRIAMYCIN.

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

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

If planning for conception, it is advisable to seek genetic counselling.

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

ADRIAMYCIN 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 ADRIAMYCIN on your blood, liver and heart regularly by giving you tests.

Women should use a reliable method of contraception (birth control) during treatment and for at least 6 months

and 10 days after last dose and men for at least 3 months and 10 days after last dose

If you become pregnant while on treatment with ADRIAMYCIN, 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 ADRIAMYCIN, 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 ADRIAMYCIN.

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 ADRIAMYCIN 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 ADRIAMYCIN. This may occasionally last for several days
- ADRIAMYCIN 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 ADRIAMYCIN. This pain will normally subside within 10 days
- hair loss is expected 1 to 2 weeks after beginning treatment with ADRIAMYCIN. 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 ADRIAMYCIN 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 ADRIAMYCIN 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. ADRIAMYCIN 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 ADRIAMYCIN 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.

After using ADRIAMYCIN

Storage

This medicine will be stored in the hospital pharmacy.

Vials of ADRIAMYCIN should be kept in a refrigerator (2°C to 8°C).

Do not freeze. Protect from light.

Product description

What it looks like

ADRIAMYCIN injection is a clear red solution. There is one vial in each pack.

Ingredients

The active ingredient in ADRIAMYCIN is doxorubicin hydrochloride. It also contains hydrochloric acid, sodium chloride and water for injections.

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

Supplier

ADRIAMYCIN is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll free number: 1800 675 229

www.pfizer.com.au

ADRIAMYCIN can be identified by the Australian Register Number which is found on the carton.

10 mg/5 mL: AUST R 15407 (not currently supplied)

20 mg/10 mL: AUST R 47344 (not currently supplied)

50 mg/25 mL: AUST R 47345

200mg/100mL: AUST R 47345

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