

ADRIAMYCIN® INJECTION

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

ADRIAMYCIN is usually given as an injection or infusion into a vein. It might also be infused into the bladder.

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 the full course of treatment with the maximum dose of ADRIAMYCIN or daunorubicin
- 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 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.

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
- some medicines used to prevent blood clots, such as heparin

- propranolol and other medicines for your heart.

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.

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.

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.

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

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 and abdominal pain may be experienced
- 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 also expected 1 to 2 weeks after you begin treatment with ADRIAMYCIN. You may lose all your hair, but after the treatment is stopped, your hair is

expected to grow back. Scalp tourniquets, worn at the time ADRIAMYCIN is given to you, may help to reduce the extent of hair loss. Male patients may notice lack of beard growth during treatment

- skin infections or blisters may also occur after treatment with ADRIAMYCIN
- bleeding or easy bruising.

Infertility is common in both men and women given ADRIAMYCIN. Women may also stop menstruating whilst they are given ADRIAMYCIN. Regular menstruation usually returns a few months after treatment is stopped in premenopausal women, although premature menopause can occur.

Men given ADRIAMYCIN may permanently experience a low sperm count or remain infertile. Sometimes male fertility may return several years after stopping ADRIAMYCIN therapy. Men should use a reliable method of contraception (birth control) during treatment with ADRIAMYCIN.

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 may occur. This may be extremely tender when touched
- infections, fever, sweats, severe chills, bruising more easily than normal. The most serious effects that may occur are a severe reduction in the body's ability to make

new red and white blood cells, which may allow an infection

- 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

Less common side effects include:

- permanent darkening of areas on the skin, nailbeds, and the inside of the mouth
- discharge with itching of the eyes and crusty eyelids
- excess tears
- redness of the skin on your fingers or toes
- redness and pins and needles on the palms of your hands and soles of your feet
- bleeding or ulceration of the bowel
- drowsiness, unusual tiredness, weakness, feeling unwell, hot flushes, shock
- blood poisoning
- kidney problems
- blockage of a blood vessel caused by a clot

- painful swelling of joints (gout)
- 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.

Product description

What it looks like

ADRIAMYCIN injection is a clear red solution.

Identification

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

10 mg / 5 mL - AUST R 15407

20 mg / 10 mL - AUST R 47344

50 mg / 25 mL and 200mg / 100mL - AUST R 47345

Ingredients

The active ingredient in ADRIAMYCIN Injection is Doxorubicin hydrochloride. It also contains sodium chloride as an inactive ingredient.

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

Supplier

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Toll free number 1800 675 229

This leaflet was revised on 6 July 2007.

© Pfizer Australia Pty Ltd

® Registered Trademark