ADRIAMYCIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given ADRIAMYCIN?

ADRIAMYCIN contains the active ingredient doxorubicin hydrochloride. ADRIAMYCIN is used to treat different types of cancers including leukaemia and cancers in breast, lymph nodes, lung, thyroid, liver, kidney, bladder or ovary. ADRIAMYCIN works by stopping cancer cells from growing and multiplying.

For more information, see Section 1. Why am I being given ADRIAMYCIN? in the full CMI.

2. What should I know before I am given ADRIAMYCIN?

You should not be given this medicine if you have ever had an allergic reaction to ADRIAMYCIN or any of the ingredients listed at the end of the CMI or any other cancer medication e.g. daunorubicin, epirubicin, mitozantrone.

You should not be given this medicine if you have a severe reduction in blood cell count, severe heart disease, a severe infection or severe liver disease. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given ADRIAMYCIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ADRIAMYCIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is ADRIAMYCIN given?

ADRIAMYCIN is injected slowly into a vein or into the bladder. It must only be given by a doctor or nurse. Your doctor will decide what dose, how often and how long you will receive it. More instructions can be found in Section 4. How is ADRIAMYCIN given? in the full CMI.

5. What should I know while being given ADRIAMYCIN?

Things you should do	• Remind any doctor or dentist you visit that you are being given

	ADRIAMYCIN solution for injection. • Tell your doctor immediately if you become pregnant while being treated with ADRIAMYCIN. If you have the potential to fall pregnant, you must use effective contraception during treatment and for at least 6 months and 10 days after your final dose. If you are male and your partner has the potential to fall pregnant, you must use effective contraception during your treatment and for 3 months and 10 days after your final dose. • Tell your doctor if you experience any signs of infection, such as sinusitis, tooth abscess, sore red mouth, fever, sore throat, unusual bleeding or bruising, swollen joints, nausea, vomiting, especially if it lasts for 24 to 48 hours.

Things you should not do	• You should not be given this medicine if you are pregnant or you or your partner are planning to become pregnant. • Do not breastfeed during treatment with ADRIAMYCIN and for at least 10 days after your final dose.

For more information, see Section 5. What should I know while being given ADRIAMYCIN in the full CMI.

6. Are there any side effects?

Common side effects of this medicine may include: infection, heart problems, difficulty in breathing, swelling of the feet, legs or stomach, unusual bruising or bleeding, nausea, vomiting, diarrhoea or abdominal pain, sore throat or mouth ulcers, sores in mouth and on lips, hair loss, darkening or redness of the skin, rash, fever, pain, redness or pain where the injection is being given. Also, this medicine may colour your urine red for 1-2 days after treatment.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ADRIAMYCIN

Active ingredient(s): doxorubicin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using **ADRIAMYCIN**. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ADRIAMYCIN.**

Where to find information in this leaflet:

1. Why am I being given ADRIAMYCIN?
2. What should I know before I am given ADRIAMYCIN?
3. What if I am taking other medicines?
4. How is ADRIAMYCIN given?
5. What should I know while being given ADRIAMYCIN?
6. Are there any side effects?
7. Product details

1. Why am I being given ADRIAMYCIN?

ADRIAMYCIN contains the active ingredient doxorubicin hydrochloride and belongs to a group of anticancer medicines known as cytotoxic anthracycline.

Doxorubicin hydrochloride works by preventing the growth of cancer cells and eventually destroying them. It is used to treat different types of cancers including

leukaemia, soft tissue & bone sarcomas and cancers in breast, lymph nodes (Hodgkin's or Non-Hodgkin's), lung, thyroid, liver, kidney, bladder or ovary.

2. What should I know before I am given ADRIAMYCIN?

Warnings

You should not be given ADRIAMYCIN if:

- you have an allergy to doxorubicin or any of the ingredients listed at the end of this leaflet
- you are allergic to medicines from the same group (anthracyclines or anthracenediones) (e.g. daunorubicin, epirubicin, idarubicin, mitozantrone or mitomycin C) or if you have previously received the total permissible dose of doxorubicin or another medicine from the anthracycline group
- 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 heart disease or heart problems, have recently had a heart attack or experienced chest pain or have a severe form of irregular heartbeats (arrhythmia)
- you have a generalised infection
- you have severe liver impairment

- you have a tumour that has penetrated the bladder wall, a urinary infection, bladder inflammation, a catheter in the bladder due to extremely large tumours or blood in your urine)
- if you are pregnant or breastfeeding

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

You should not be given this medicine if you or your partner are pregnant or planning to become pregnant.

You are advised to avoid pregnancy during treatment as it may harm your developing baby.

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

Doxorubicin is known to pass into breast milk. Therefore, you 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.

Contraception

Women of childbearing potential should use effective contraception during treatment with doxorubicin and for at least 6 months and 10 days after the final dose. Male patients being treated with doxorubicin must use

effective contraception during treatment and for at least 3 months and 10 days after the final dose if your partner is of childbearing potential. You should seek advice on fertility preservation before treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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 cancer medicines, such as cyclophosphamide monohydrate, paclitaxel, 6-mercaptopurine, sorafenib
- some medicines used to prevent blood clots, such as heparin
- propranolol and other medicines for your heart.
- verapamil used for high blood pressure, angina or irregular heartbeat
- phenobarbital and phenytoin used to treat epilepsy
- St. John's Wort, a herbal supplement, used for mild anxiety and low mood
- ciclosporin 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.

Avoid vaccination with certain vaccines. Your doctor or pharmacist will tell you what vaccines to avoid.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ADRIAMYCIN.

4. How is ADRIAMYCIN given?

How much and how long is it 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 healthcare professionals.

ADRIAMYCIN is given in a clinical setting by a nurse or doctor.

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

Your doctor will decide what dose, how often and how long you will receive it. 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 other medicines are being given at the same time.

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.

Treatment is usually given once every 3 weeks, or on 3 successive days repeated every 4 weeks. However, your doctor may give ADRIAMYCIN more or less frequently.

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

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

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

If too much ADRIAMYCIN is given

Since ADRIAMYCIN is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

If you think that you have been given too much ADRIAMYCIN, you may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in Section 6 Are there any side effects? but are usually of a more severe nature.

Immediately tell your doctor or telephone the Poisons Information Centre (Phone 13 11 26) for advice or go to Accident and Emergency at your

nearest hospital if you have side effects after being given ADRIAMYCIN.

5. What should I know while being given ADRIAMYCIN?

Things you should do

Keep all your doctor's appointments.

You will need regular follow-up to check your progress.

You will also have blood tests and heart monitoring to check for side effects.

Tell your doctor immediately if you become pregnant while being treated with ADRIAMYCIN.

Call your doctor straight away if you experience any of the following during or after treatment:

- stinging, burning or pain develops at the injection site
- any signs of infection, such as sinusitis, tooth abscess, sore red mouth, fever, sore throat
- unusual bleeding or bruising
- gout, a disease with painful, swollen joints
- nausea, vomiting, especially if it lasts for 24 to 48 hours.

Treatment with doxorubicin can cause bone marrow damage, which can result in infections and/or severe bleeding. Your doctor will closely monitor your blood cell

levels to be able to respond quickly and start treatment if these conditions occur.

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 clippers
- 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.

Tell your doctor if you are having or have had radiotherapy.

Tell your doctor if you are having or have had treatment with other anticancer medicines.

Tell your doctor if you have liver problems or kidney problems.

You should not be given this medicine if you have severe liver problems. Your doctor may need to monitor your liver or kidney function and adjust the doxorubicin dose if necessary.

Tell your doctor if you have or have had heart disease or have high blood pressure.

Tell any doctors, dentists or pharmacists who treat you that you are being treated with ADRIAMYCIN.

Women of childbearing potential should use effective contraception during treatment and for at least 6 months and 10 days after the final dose. Male patients being treated must use effective contraception during treatment and for at least 3 months and 10 days after the final dose if your partner is of childbearing potential.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ADRIAMYCIN affects you.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects	**What to do**
• nausea, vomiting • diarrhoea, dehydration, flushing of the face (hot and red), abdominal pain • skin infections, blisters, itchy skin • darkening of areas on the skin, nail beds, and the inside of the mouth • bleeding or easy bruising • discharge with itching of the eyes and crusty eyelids, dry eyes or excess tears • a burning sensation in the mouth, throat, food pipe, rectum or vagina	**Speak to your doctor if you have any of these side effects and they worry you.**

Side effects	What to do
• reddish urine (this medicine may colour your urine red for 1-2 days after treatment). • hair loss on all parts of the body • loss of appetite • redness or pins and needles on the palms of your hands and soles of your feet • drowsiness, unusual tiredness, weakness, feeling unwell, hot flushes • painful swelling of joints (gout) • weight gain • infertility in both men and women	

Serious side effects	What to do
• swelling, redness or tenderness of skin along the vein • burning, stinging, hotness, redness or pain	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
where the injection is being given • infections, fever, sweats, severe chills • unusual bruising or bleeding • fatigue, chest pain, palpitations, shortness of breath or swelling in the feet or legs due to fluid build-up. • abdominal pain, bleeding or ulceration of bowel **If you are given ADRIAMYCIN into the bladder, tell your doctor as soon as possible if you develop the following temporary side effects:** • pain in the bladder or back, blood in urine • difficulty passing urine or an increased frequency of passing urine	**notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ADRIAMYCIN contains

Active ingredient **(main ingredient)**	Doxorubicin hydrochloride
Other ingredients **(inactive ingredients)**	Hydrochloric acid Sodium chloride Water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What ADRIAMYCIN looks like

ADRIAMYCIN is a clear red solution in a clear vial.

Australian Registration Numbers

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

200 mg/100 mL: AUST R 47345

Who distributes ADRIAMYCIN

Pfizer Australia Pty Ltd

SYDNEY, NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au

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