

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 using CAELYX?

CAELYX contains the active ingredient doxorubicin hydrochloride. CAELYX is used to treat cancer of the breast and ovary. It is used to kill cancer cells, shrink the size and delay the growth of the tumour.

For more information, see Section [1. Why am I using CAELYX?](#) in the full CMI.

2. What should I know before I use CAELYX?

Do not use if you have ever had an allergic reaction to CAELYX or any of the ingredients listed at the end of the CMI.

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 use CAELYX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CAELYX 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 do I use CAELYX?

- CAELYX will be given to you by your doctor in a drip (infusion) into a vein.
- Depending on the dose and indication, this may take from 30 minutes to more than one hour (i.e., 90 minutes).

More instructions can be found in Section [4. How do I use CAELYX?](#) in the full CMI.

5. What should I know while using CAELYX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CAELYX.• 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.
Things you should be careful of	<ul style="list-style-type: none">• If you get reddening painful skin on your hands and feet, tightness in the chest, shortness of breath, any heart problems or mouth sores or if you develop a temperature or any sign of an infection while being given, or soon after stopping CAELYX, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery, if you feel light-headed or sleepy.
Drinking alcohol	<ul style="list-style-type: none">• It is not recommended that you drink alcohol while using CAELYX.
Looking after your medicine	<ul style="list-style-type: none">• CAELYX will be stored in the pharmacy or on the ward and looked after by your doctor, pharmacist or nurse. CAELYX is a concentrated suspension for infusion and is stored at 2°C to 8°C in the refrigerator. Do not freeze.

For more information, see Section [5. What should I know while using CAELYX?](#) in the full CMI.

6. Are there any side effects?

Some of the common and less serious side effects weakness, headache, backpain, low blood pressure, chest/throat tightness, face puffing, skin swelling, fits, weight loss, sickness, diarrhoea, constipation, anxiety, and taste perversion. Some of the uncommon/ rare and serious side effects are irregular heartbeat, shortness of breath, swelling of feet/hands, fever, severe chills, sore throat/mouth ulcers, cough, pain/difficulty/increased frequency of passing urine, sore/red nose, tiredness, redness, swelling and sores on the palms of your hands/feet, fungal infection in the mouth, tongue inflammation, sore/irritated eyes, bruising easily than normal, pain, redness, and dryness of skin.

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.

CAELYX

Active ingredient(s): *doxorubicin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CAELYX.

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 CAELYX.

Where to find information in this leaflet:

- [1. Why am I using CAELYX?](#)
- [2. What should I know before I use CAELYX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CAELYX?](#)
- [5. What should I know while using CAELYX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CAELYX?

CAELYX contains the active ingredient **doxorubicin hydrochloride**. CAELYX is used to treat cancer of the breast and ovary. It is used to kill cancer cells, shrink the size and delay the growth of the tumour.

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

CAELYX is also used to treat **Kaposi's Sarcoma**, another type of cancer. CAELYX produces an improvement in **Kaposi's Sarcoma** including flattening, lightening and shrinkage of the cancer. Other symptoms of **Kaposi's Sarcoma**, such as swelling around the tumour, may also improve or disappear.

CAELYX is also used in combination with another medicine called **bortezomib** to treat multiple myeloma, which is a cancer of the plasma cell. Plasma cells are produced in the bone marrow and are a component of the immune system.

CAELYX contains a medicine called **doxorubicin hydrochloride** which is able to interact with cells in such a way as to selectively kill cancer cells. The **doxorubicin hydrochloride** in CAELYX is enclosed in tiny spheres called **liposomes** which help to deliver the medicine from the blood stream to the cancerous tissue rather than healthy normal tissue.

Your doctor, however, may prescribe CAELYX for another purpose.

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

2. What should I know before I use CAELYX?

Warnings

Do not use CAELYX if:

- you are allergic to doxorubicin hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you have a history of hypersensitivity reactions to its components or to doxorubicin hydrochloride.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition.

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

Tell your doctor if you are pregnant/planning to become pregnant or breast-feeding.

CAELYX is not recommended in pregnancy and breast-feeding. Your doctor will discuss the possible risks and benefits of using CAELYX during pregnancy and breast-feeding.

Do not use CAELYX if you are pregnant or breast-feeding.

It is important that you or your partner use a reliable method of contraception to avoid pregnancy during CAELYX treatment and 8 months for female and 6 months for male after treatment is stopped.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems
- liver problems
- diabetes
- recent surgery to remove your spleen.

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 may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when being given CAELYX with other medicines.

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

4. How do I use CAELYX?

How much to use

- CAELYX is normally administered to you by doctors or nurses in hospital.
- Your doctor will decide how much CAELYX you will be given and for how long.
- The usual dose for cancer of the breast or ovary is 50 mg per square metre of body surface area. This dose is repeated every four weeks for as long as the disease does not progress and you are able to tolerate the treatment.
- For multiple myeloma the usual dose is 30 mg per square metre of body surface area. This dose is repeated every three weeks as long as the disease has a satisfactory response and you are able to tolerate the treatment.
- For Kaposi's sarcoma the usual dose is 20 mg per square metre of body surface area. This dose is repeated every 2 to 3 weeks for 2-3 months, then as often as necessary to maintain an improvement.

When to use CAELYX

- Doxorubicin Baxter pegylated liposomal will be given to you by your doctor in a drip (infusion) into a vein. Depending on the dose and indication, this may take from 30 minutes to more than one hour (i.e., 90 minutes).

If you use too much CAELYX

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using CAELYX?

Things you should do

Call your doctor straight away if you:

- If the drip stings or hurts while you are receiving a dose of CAELYX
- If the medicine starts to upset you or your symptoms become worse

Be sure to keep all 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 your follow-up doses of CAELYX at the appropriate times to get the best effects from your treatments.

Tell any other doctors, dentists, and pharmacists who are treating you that you are on CAELYX treatment.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are on CAELYX treatment.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are on CAELYX treatment.

Tell your doctor, if you become pregnant during CAELYX treatment or 8 months after treatment is stopped.

CAELYX can lower 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. The following precautions should be taken 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 tooth brush, 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.

Things you should be careful of

If you get reddening painful skin on your hands and feet, tightness in the chest, shortness of breath, any heart problems or mouth sores or if you develop a temperature or any sign of an infection while being given, or soon after stopping CAELYX, tell your doctor immediately.

CAELYX exhibits unique pharmacokinetic properties and must not be used interchangeably with other formulations of doxorubicin HCl.

Driving or using machines

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

CAELYX may cause dizziness, tiredness or sleepiness in some people. Make sure you know how you react to CAELYX before you drive a car, operate machinery, or do anything else that could be dangerous if you are light-headed or sleepy.

Do not drive or operate machinery, if you feel light-headed or sleepy.

Drinking alcohol

Tell your doctor if you drink alcohol.

It is not recommended that you drink alcohol while using CAELYX.

Looking after your medicine

This medicine is a concentrated suspension for infusion and will be stored in the hospital pharmacy or in the ward and looked after by your doctor, pharmacist or nurse. It will be kept in original packaging and stored at 2°C to 8°C in the refrigerator. Do not freeze.

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
<p>Skin – related:</p> <ul style="list-style-type: none"> • stinging or swelling of the skin at the site of injection <p>Pain – related:</p> <ul style="list-style-type: none"> • headache, • backpain, • tightness in the chest and/or throat <p>Body as a whole:</p> <ul style="list-style-type: none"> • flushing of the face • chills • shortness of breath • low blood pressure • possibly dizziness • puffing of the face • convulsions or fits. 	<p>Tell your doctor, nurse or pharmacist if you notice any of the above reactions or if the drip stings or hurts while you are receiving CAELYX.</p>

Serious side effects

Serious side effects	What to do
<p>Skin – related:</p> <ul style="list-style-type: none"> • dark or pale areas of skin • skin rash • stomach pains 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

<p>Pain – related:</p> <ul style="list-style-type: none"> • sore muscles • back pain <p>Body as a whole:</p> <ul style="list-style-type: none"> • tiredness • sleepiness or weakness • loss of appetite • weight loss • sickness (nausea and vomiting) • diarrhoea • constipation • hair loss, • depression or anxiety • taste perversion 	<p>your nearest hospital if you notice any of these serious side effects.</p>
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Very Serious side effects

Very Serious side effects	What to do
<p>Allergy or reaction – related:</p> <ul style="list-style-type: none"> • Sudden signs of allergy such as swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, shortness of breath, skin problems such as rash or itchy pinkish, itchy swellings on the skin, also called hives or nettle rash • dizziness, light-headedness, fainting. <p>Heart – related:</p> <ul style="list-style-type: none"> • Irregular heart beat <p>Body as a whole:</p> <ul style="list-style-type: none"> • shortness of breath • swelling of feet or hand • fever • severe chills • sore throat or mouth ulcers • persistent cough, • pain/difficulty or increased frequency of passing urine • sore or red nose • signs of anaemia, such as tiredness, being short of breath, and looking pale • redness, swelling and sores on the palms of your hands and feet • sores in the mouth, oral thrush (a fungal infection in the mouth), tongue inflammation • problems with vision, sore or irritated eyes • feelings of pins and needles <p>Skin – related:</p> <ul style="list-style-type: none"> • Pain • redness and 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • dryness of skin • skin peeling • scaly skin lesions 	
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NSW 2146, Australia

Toll Free Number: 1800 229 837

www.baxterhealthcare.com.au

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

Other side effects not listed here may occur in some people.

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 CAELYX contains

Active ingredient (main ingredient)	Pegylated liposomal doxorubicin hydrochloride (2 mg per 1 mL)
Other ingredients (inactive ingredients)	sodium methoxy PEG-40-carbonyl-distearoylphosphatidyl-ethanolamine (MPEG-DSPE), hydrogenated soy phosphatidylcholine (HSPC), cholesterol, ammonium sulfate, sucrose, histidine, Water for Injections, hydrochloric acid and sodium hydroxide
Potential allergens	Soya bean product

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

What CAELYX looks like

CAELYX comes as a sterile, translucent red suspension (2 mg per 1 mL) in a glass vial. It is available as 20 mg/10 mL (AUST R 60384) or 50 mg/25 mL (AUST R 79921) vials with one vial inside each pack.

Who distributes CAELYX

Baxter Healthcare Pty Ltd

1 Baxter Drive

Old Toongabbie

This leaflet was prepared in January 2026.