

CAELYX[®]

pegylated liposomal doxorubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CAELYX. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using CAELYX against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What CAELYX is used for

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

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.

Before you are given CAELYX

When you must not be given it

Do not use CAELYX if you have an allergy to CAELYX, doxorubicin hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin.

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

Before you are given it

Your doctor must know about all of the following before you are given CAELYX.

Tell your doctor or pharmacist if you have allergies to:

- any medicines (including other anti-cancer medicines)
- any other substances, such as foods, preservatives or dyes

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.

Tell your doctor if you have had any or are on other anti-cancer medicines.

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.

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

If you have not told your doctor about any of the above, tell

them before you are given CAELYX.

Taking or being given other medicines

Tell your doctor 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 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.

How CAELYX is given

CAELYX is given by your doctor in a drip (called an infusion) into a vein. Depending on the dose this may take from 30 minutes to more than one hour.

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.

Overdose

As CAELYX is given to you 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 CAELYX, tell your doctor immediately.

You may need urgent medical attention.

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

While you are using CAELYX

Things you must do

If the drip stings or hurts while you are receiving a dose of CAELYX, tell your doctor immediately.

If the medicine starts to upset you or your symptoms become worse, tell your doctor.

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 or your partner become pregnant during CAELYX treatment or 6 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 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.**

Things to be careful of

Be careful driving or operating machinery 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.

If you get reddening painful skin on your hands and feet, 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.

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given CAELYX.

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.

Ask your doctor or pharmacist to answer any questions you may have.

During the infusion of CAELYX the following reactions may occur:

- flushing of the face, shortness of breath, headache, chills, back pain, tightness in the chest and/or throat, low blood pressure and possibly dizziness and puffing of the face.
- stinging or swelling of the skin at the site of injection may also occur.
- convulsions or fits.

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.

Tell your doctor if you notice any of the following and they

worry you. These are the more common side effects of CAELYX:

- general feeling of tiredness, sleepiness or weakness
- loss of appetite, weight loss
- stomach pains, sickness (nausea and vomiting), diarrhoea, constipation
- hair loss, skin rash
- depression or anxiety
- sore muscles or back pain
- taste perversion
- dark or pale areas of skin.

These are some of the more common side effects of CAELYX.

Tell your doctor immediately if you notice any of the following.

These are the more serious side effects. You may need urgent medical attention.

- heart problems such as irregular heart beat, shortness of breath and/or swelling of feet or hands
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers, persistent cough, pain/difficulty or increased frequency of passing urine, sore or red nose
- bruising more easily than normal
- 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
- respiratory problems such as difficulty in breathing which may be linked to infections you have caught as a result of your disease
- problems with vision, sore or irritated eyes
- feelings of pins and needles

- pain, redness and dryness of skin if previously experienced during treatment with radiotherapy may also happen with CAELYX.

A few people may be allergic to some medicines.

Tell your doctor or nurse immediately if you notice any of the following:

- 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 itchiness
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- dizziness, light-headedness, fainting.

If you have these, you may have had a serious allergic reaction to CAELYX. You may need urgent medical attention.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After CAELYX has been stopped

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with CAELYX.

- any heart problems such as shortness of breath or irregular heart beat
- fever or any other sign of infection
- redness, swelling or sores on the palms of hands and feet.

Tell your doctor if you notice any other effects.

Tell your doctor, if you or your partner become pregnant during the 6 months after CAELYX treatment is stopped.

Storage

CAELYX will be stored in the pharmacy or on the ward and looked after by your doctor, pharmacist or nurse.

This medicine is a concentrated suspension for infusion and is stored at 2°C to 8°C in the refrigerator. Do not freeze.

Do not use CAELYX if the expiry date (EXP) printed on the pack has passed.

Product Description

What it 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 or 50 mg/25 mL vials with one vial inside each pack.

Ingredients

Active ingredient:

Pegylated liposomal doxorubicin hydrochloride (2 mg per 1 mL)

Inactive ingredients:

- sodium methoxy PEG-40-carbonyl-distearoylphosphatidylethanolamine (MPEG-DSPE)
- hydrogenated soy phosphatidylcholine (HSPC)
- cholesterol
- ammonium sulfate
- sucrose
- histidine
- Water for Injections
- hydrochloric acid
- sodium hydroxide

Sponsor

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Australian Registration Number

CAELYX 20 mg/10 mL:
AUST R 60384

CAELYX 50 mg/25 mL:
AUST R 79921

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