

PART III: CONSUMER INFORMATION



Pegylated Liposomal Doxorubicin Hydrochloride for Injection

This leaflet is part III of a three-part "Product Monograph" published when CAELYX® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CAELYX®. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start using this medicine. Keep this leaflet. You may need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:

- Patients with metastatic breast cancer who are at risk for heart problems associated with conventional doxorubicin;
- Patients with advanced ovarian cancer who have not been successfully treated with standard first-line chemotherapy;
- Patient with AIDS-related Kaposi's sarcoma who have a low number of a specific type of white blood cell (CD4 lymphocytes) and extensive skin and mucous membrane or internal organ disease which has progressed despite therapy or who are intolerant to prior systemic combination chemotherapy.

What it does:

CAELYX® contains a medicine 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 pegylated liposomes which help to deliver the medicinal product from the blood stream to the cancerous tissue.

When it should not be used:

- If you are hypersensitive (allergic) to doxorubicin hydrochloride or any of the other ingredients of CAELYX®.
- If you are breast-feeding. Because doxorubicin hydrochloride may be harmful to nursing infants, women must discontinue breast-feeding before starting treatment with CAELYX®. Health experts recommend that HIV infected women do not breast-feed their infants under any circumstances in order to avoid transmission of HIV
- If you think you are pregnant, because the active ingredient doxorubicin hydrochloride in CAELYX® may cause birth defects. Avoid becoming pregnant while you or your partner are receiving CAELYX® and in the six months following discontinuation of CAELYX® treatment.

What the medicinal ingredient is:

CAELYX® is pegylated liposomal doxorubicin hydrochloride. The active substance is doxorubicin hydrochloride in a pegylated liposomal formulation in a 2 mg/mL concentrate suspension for infusion.

What the important nonmedicinal ingredients are:

The STEALTH® liposome carriers are composed of N-(carbamoyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-

sn-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE), 3.19 mg/mL; fully hydrogenated soy phosphatidylcholine (HSPC), 9.58 mg/mL; and cholesterol, 3.19 mg/mL. Each mL also contains approximately 2 mg of ammonium sulfate; 1.55 mg of histidine as a buffer; hydrochloric acid and/or sodium hydroxide for pH control and 94 mg of sucrose to maintain isotonicity. Greater than 90% of the drug is encapsulated in the STEALTH® liposomes.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

CAELYX® should be prescribed and managed by healthcare professional specialized in the use of cancer drugs.

Possible serious side effects with the use of CAELYX® include:

- Heart damage, including congestive heart failure and weakening of heart muscle;
- Acute infusion reaction;
- Decrease of blood cell production (myelosuppression);
- Secondary oral cancer including fatal cases.

BEFORE you use CAELYX® talk to your doctor or pharmacist:

- If you have any of the following conditions. The dose of CAELYX® may need to be adjusted:
 - Previous treatment with anthracyclines (doxorubicin, epirubicin, etc.);
 - Chest radiation;
 - Heart and blood vessel problems;
 - Liver problems or disease;
- If you are diabetic, because CAELYX® contains sugar which may require an adjustment to the treatment of your diabetes.
- If you have a history of myelosuppression;
- If you think you are pregnant, or are breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Please inform your doctor and pharmacist:

- If you are taking or have recently taken any other medicines, even those not prescribed
- About any other cancer treatments you are on or have been taking, as particular care needs to be taken with treatments which reduce the number of white blood cells. If you are unsure about what treatments you have received or any illnesses you have had, discuss these with your doctor.

PROPER USE OF THIS MEDICATION

Usual dose:

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).

If you are being treated for breast or ovarian cancer, CAELYX® will be administered at a dose of 50 mg per square meter of your body surface area (based on your height and weight). The dose is

repeated every 4 weeks for as long as the disease does not progress and you are able to tolerate the treatment.

If you are being treated for Kaposi's sarcoma, CAELYX® will be administered at a dose of 20 mg per square metre of your body surface area (based on your height and weight). The dose is repeated every 2 to 3 weeks.

Overdose:

If You Receive More CAELYX® Than You Should:

Acute overdosing worsens side effects like sores in the mouth or decrease in the number of white blood cells and platelets in the blood. Treatment will include administration of antibiotics, platelet transfusions, use of factors which stimulate production of white blood cells and symptomatic treatment of mouth sores.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Do not drive or operate any tools or machines if you feel tired or sleepy from treatment with CAELYX®.

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 or high blood pressure and puffing of the face. In very rare cases, seizures (convulsions) have occurred. Stinging or swelling of the skin at the site of injection may also occur. If the drip stings or hurts while you are receiving a dose of CAELYX®, tell your doctor immediately.

Opportunistic infections are otherwise rare infections that typically do not occur in healthy people, and develop because the immune system is weak. The commonly reported opportunistic infections during CAELYX® treatment include fungal (candidiasis), cytomegalovirus (CMV), *Pneumocystis carinii* pneumonia (PCP), and *Mycobacterium avium* complex (MAC) infections.

Between infusions, the following may occur:

- Decrease in the number of white blood cells, which can increase the chances of infections. Anemia (reduction in red blood cells) may cause tiredness, and decreased platelets in the blood may increase the risk of bleeding. In rare cases, having low white blood cells may lead to severe infection.
- Change in liver function;
- Stomach pains/sickness (nausea or vomiting), diarrhea, constipation, pain or sores in mouth, oral thrush (a fungal infection in the mouth), sores in nose, bleeding from your nose, cold sores, loss of appetite, weight loss and tongue inflammation;
- General feeling of tiredness, sleepiness, confusion, dizziness, weakness, bone pain, breast pain, muscle pain, leg cramps or swelling, general swelling, inflammation of the retina, tearing of the eye, blurred vision, feeling of pins and needles or pain in hands and feet;
- Hair loss, inflammation of hair follicles, scaly skin, inflammation or eruption of skin, abnormal skin pigmentation,

- nail disorder, and rash, redness, swelling and sores on the palms of your hands and feet (hand-foot syndrome - see below);
- Heart problems, e.g., irregular heartbeat, weakening of the heart muscle;
- Fever, increased temperature or any other sign of infection which may be related to your disease;
- Respiratory problems, i.e., coughing or difficulty in breathing, which may be linked to infections you have caught as a result of your disease;
- If you have previously had skin reactions, i.e., pain, redness and dryness of skin, during treatment with radiotherapy, this may also happen with CAELYX®.

Contact your doctor immediately if:

- you get reddening, painful skin on your hands and feet;
- you get sudden shortness of breath or sharp chest pain that may worsen with deep breathing or coughing;
- you get painful reddening of the skin and/or blister on the body or the mouth;
- you get mouth sores;
- you develop a fever or any other sign of an infection;
- you get swelling, warmth, or tenderness in the soft tissues of your leg, sometimes with pain which gets worse when you stand or walk.

Strategies to Prevent and Treat Hand-Foot Syndrome

- Soak hands and/or feet in basins of cold water when possible (e.g., while watching television, reading, or listening to the radio);
- Keep hands and feet uncovered (no gloves, socks, etc.);
- Stay in cool places (under tree shade, by a swimming area with shade etc.);
- Take cool baths or stay in the water during the summer;
- Avoid vigorous exercise that might cause trauma to the feet (e.g. jogging);
- Avoid exposure of skin to very hot water (e.g., jacuzzis, saunas);
- Avoid tight-fitting footwear or high-heeled shoes.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common Allergic-like reactions (during infusion) such as flushing of the face, shortness of breath, headache, chills, tightness in the chest and/or throat, low or high blood pressure and possibly dizziness and puffing of the face, stinging or swelling of the skin at the site of injection; If the drip stings or hurts while you are receiving a dose of CAELYX®; Reddening painful skin on your hands and feet; Heart problems such as irregular heartbeat, shortness of breath and/or swelling of feet or hands; Fever or any other sign of an infection, bruising more easily than normal, signs of anemia such as tiredness, being short of breath, and looking pale; Mouth sores.		✓	
		✓	
		✓	
		✓	
		✓	
		✓	
Uncommon Swelling, warmth, or tenderness in the soft tissues of your leg, sometimes with pain which gets worse when you stand or walk; Sudden shortness of breath or sharp chest pain that may worsen with deep breathing or coughing.		✓	
		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Rarely Convulsion during infusion reactions; Painful reddening of the skin and or blister on the body or mouth.		✓	
		✓	
Reported from post-marketing with unknown frequency Oral cancer may occur during or following treatment with CAELYX®. Mouth discoloration, discomfort, sores or ulcerations should be reported to your doctor.		✓	

This is not a complete list of side effects. For any unexpected effects while taking CAELYX®, contact your doctor or pharmacist.

HOW TO STORE IT

Keep CAELYX® out of reach and sight of children.

Do not use if CAELYX® solution is discolored or shows evidence of precipitation or particles.

CAELYX® should be stored in the refrigerator (2°C – 8°C). Do not freeze. Discard partially used vials.

Diluted CAELYX® should be refrigerated and used within 24 hours.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.janssen.com/canada>

or by contacting the sponsor, Janssen Inc.

at: 1-800-567-3331 and 1-800-387-8781

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