PART III: CONSUMER INFORMATION

PrHYCAMTIN®
topotecan hydrochloride for injection

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

You may want to read this leaflet again. **Please Do Not Throw It Away,** until you have finished your medicine.

ABOUT THIS MEDICATION

What the medication is used for:
HYCAMTIN (topotecan hydrochloride) is used for the treatment of:

- ovarian cancer (metastatic) after failure of initial or subsequent therapy.
- sensitive small cell lung cancer after failure of first line chemotherapy (defined as recurrence at least 60 days after first line chemotherapy).

What it does:
HYCAMTIN helps destroy tumours. It acts on an enzyme (topoisomerase-I) to prevent growth of tumour cells.

When it should not be used:
Do not take HYCAMTIN if:

- you are hypersensitive (allergic) to topotecan or any of the other ingredients of HYCAMTIN.
- you are pregnant or breast-feeding.
- you have severe kidney disease.
- results of your last blood test show that you are not able to receive HYCAMTIN (severe bone marrow depression). Your doctor will tell you.

What the medicinal ingredient is:
The medicinal ingredient is topotecan hydrochloride.

What the important nonmedicinal ingredients are:
The nonmedicinal ingredients consist of mannitol, tartaric acid, hydrochloric acid and sodium hydroxide.

What dosage forms it comes in:
HYCAMTIN (topotecan hydrochloride) for injection is supplied as sterile powder in single-dose vials. Each vial contains 4 mg of topotecan. Before infusion the powder needs to be reconstituted and diluted.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

HYCAMTIN should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents.

Possible serious side effect includes:

- **a decrease in the number of cells produced in your bone marrow (bone marrow suppression), especially a type of white blood cells called neutrophils (neutropenia).**
- **Bowel inflammation which may cause severe pain in your abdomen, with fever and a decrease in white blood cells which can potentially be fatal (neutropenic colitis).**
- **Lung inflammation which may cause severe coughing, shortness of breath and fever which can potentially be fatal (interstitial lung disease).**

BEFORE you use HYCAMTIN talk to your doctor or pharmacist if:

- you are hypersensitive (allergic) to topotecan or any of the other ingredients of HYCAMTIN.
- you are pregnant or breast-feeding.
- results of your last blood test show that you are not able to receive HYCAMTIN, your doctor will tell you.
- you have kidney disease.

Use of this medicine during Pregnancy and Breast Feeding
You should not be given HYCAMTIN if you are pregnant or think you are pregnant.

Nursing Mothers
Do not breast-feed if you are receiving HYCAMTIN. You should not restart breast-feeding until the doctor tells you it is safe.

Use in Children
Use in children is not recommended as safety and effectiveness have not been established.

Effect on ability to drive and use machinery
HYCAMTIN may make you feel tired. Do not drive or operate any tools or machines if you feel tired or weak.

INTERACTIONS WITH THIS MEDICATION

It is important that your doctor know about all your medications so that you get the best possible treatment. Tell your doctor about all the medicines you are taking including those you have bought without a prescription.

PROPER USE OF THIS MEDICATION

Usual dose:
The dose of HYCAMTIN which you will receive will be based on your body size (surface area) and the results of blood tests carried out before treatment.

The recommended dose of HYCAMTIN is 1.5 mg/m^2 by intravenous infusion over 30 minutes daily for 5 consecutive days, starting on day one of a 21-day course. Prior to administration, HYCAMTIN powder must be dissolved with water. The HYCAMTIN solution will be diluted further using either Sodium Chloride solution or Dextrose solution. A minimum of four courses of HYCAMTIN is recommended.

Insufficient data are available in children to provide a dosage recommendation.

Remember: This medicine is for you. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are the same as yours.

Overdose:

If you think you have been given too much HYCAMTIN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre right away, even if you do not have any symptoms.

Accidental overdosage may result in low blood pressure, fast heart rate and bleeding of the bowel.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, HYCAMTIN can have side effects. The most common side effects with HYCAMTIN are:

- a temporary reduction in the amount of new blood cells produced by your body, particularly of a type of white blood cell which is important for your body to prevent and fight off an infection. In approximately 1 in 20 patients a serious infection is caught during treatment which can be fatal. If at any time during treatment you feel unwell or develop a temperature you should contact your doctor immediately.
- you may become temporarily anemic and tired or take longer for a minor injury to stop bleeding. The reduction in the amount of blood cells (lasts for only a few days), starting from approximately day 8 of each treatment cycle and lasting for about a week. In most cases the level of blood cells return to normal in time for the next cycle of treatment.
- Gastrointestinal perforations (including life-threatening and fatal cases) have been reported with HYCAMTIN-treated patients. Your doctor will monitor you for the possibility of GI perforation if you experience symptoms of severe stomach pain, nausea, vomiting and/or bloody stool and will discontinue HYCAMTIN if you have an intestinal perforation.

Other possible side effects are:

- nausea (feeling sick or queasy or having the urge to throw up)
- vomiting (throwing up)
- diarrhea (frequent and watery bowel movements)
- fever
- hair loss
- stomach pain
- constipation
- swelling and pain of the mouth, tongue or gums
- fatigue (tiredness)
- weakness
- anorexia (weight loss and loss of appetite)
- feeling unwell
- headache
- coughing
- shortness of breath
- yellow skin (jaundice)
- rash
- itching sensation
- mild pain and inflammation at the site of injection. Severe allergic reactions have been reported rarely.
- lung inflammation (interstitial lung disease) has been reported rarely. Signs include difficulty in breathing, severe cough and fever.

Several of these effects may occur during your treatment. If you notice any of these, or any other effects not mentioned in this leaflet between courses or when you leave hospital/after treatment has finished, tell your doctor, nurse or pharmacist.

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

Frequency	Side Effect/Symptom	Talk with your Doctor immediately
Very Common	Any sign of fever or infection, or any unexpected bruising or bleeding.	X
Common	Serious infection; local symptoms such as sore throat or	X

	urinary problems (for example, a burning sensation when urinating, which may be caused by a urinary infection)	
Uncommon	Severe allergic reaction and symptoms such as swelling of the mouth, throat, difficulty in breathing, rash, hives, increased heart rate, and collapse.	X
Rare	Severe bleeding.	X
	Severe abdominal pain, fever and diarrhoea (rarely with blood). These could be signs of bowel inflammation (colitis)	X
	Severe cough, shortness of breath, fever (interstitial lung disease). You are at increased risk if you have had radiation treatment to your lungs, or have previously taken medicines that caused lung damage.	X
Frequency not known (events from spontaneous reports)	Severe stomach pain, nausea, vomiting of blood, black or bloody stools. (Possible symptoms of gastrointestinal perforation).	X
	Mouth sores, difficulty swallowing, abdominal pain, nausea, vomiting, diarrhoea, bloody stool which could be signs and symptoms of inflammation of the inner lining of the mouth, stomach and / or gut (mucosal inflammation).	X

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

HOW TO STORE IT

Unopened vials of HYCAMTIN are stable until the date indicated on the package when stored between 15 and 30ºC (59º and 86ºF) and protected from light in the original package.

Reconstituted Solutions
Vials which have been reconstituted with Water for Injection are stable for up to 24 hours when refrigerated at 5ºC (41ºF) or stored at 30ºC (86ºF).

However, since the vials contain no preservative, it is recommended that the product should be used immediately after reconstitution. If not used immediately, the reconstituted solution should be stored in a refrigerator and discarded after 24 hours.

Diluted solutions
Reconstituted vials of HYCAMTIN diluted for infusion are stable for up to 24 hours at approximately 20 to 25ºC (68 to 77ºF) and ambient lighting conditions. If not used immediately, the diluted solution should be stored in a refrigerator in line with good pharmaceutical practice.

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 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.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.

NOTE: Should you require information related to the management of the 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.novartis.ca or by contacting the sponsor,

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