

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**Irinotecan Hydrochloride Injection USP**

(Irinotecan Hydrochloride Injection)

Read this carefully before you start taking **Irinotecan Hydrochloride Injection USP** and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Irinotecan Hydrochloride Injection USP**.

Serious Warnings and Precautions

Irinotecan Hydrochloride Injection USP should be given under the supervision of a healthcare professional who is experienced in the use of chemotherapy drugs.

Serious side effects with the use of Irinotecan Hydrochloride Injection USP include:

- **Diarrhea:** Severe early and late forms of diarrhea that can be life-threatening as they may lead to dehydration (fluid loss) and electrolyte (salt) imbalance.
- **Gut problems (inflammation and blockage):** Bowel inflammation (typhlitis and colitis), lack of bowel movement (ileus), or a hole in the wall of the small intestine or large bowel (intestinal perforation).
- **Infections:** Decreased production of white blood cells resulting in neutropenia (low blood level of immune cells). Cases of bacterial, fungal and viral infections, sometimes fatal and/or life-threatening.

What is Irinotecan Hydrochloride Injection USP used for?

Irinotecan Hydrochloride Injection USP is a chemotherapy drug (drug used to treat cancer), used:

- in combination with other drugs to treat cancers of the colon and rectum that have spread to other areas of the body;
- alone to treat cancers of the colon and rectum that have spread to other areas of the body and were not able to be treated effectively with 5-fluorouracil-based therapy.

How does Irinotecan Hydrochloride Injection USP work?

Irinotecan Hydrochloride Injection USP, like most chemotherapy drugs, works by killing rapidly dividing cells, such as cancer cells. In some cancers, chemotherapy can be used to reduce tumour size, or stop them from growing.

What are the ingredients in Irinotecan Hydrochloride Injection USP?

Medicinal ingredients: irinotecan hydrochloride trihydrate

Non-medicinal ingredients: lactic acid, sodium hydroxide and/or hydrochloric acid, sorbitol, water for injection

Irinotecan Hydrochloride Injection USP comes in the following dosage forms:

solution, 20 mg / mL

Do not use Irinotecan Hydrochloride Injection USP if:

- you are allergic to irinotecan hydrochloride or any of the non-medicinal ingredients in Irinotecan Hydrochloride Injection USP (see **What are the ingredients in Irinotecan Hydrochloride Injection USP?**);
- you have hereditary fructose intolerance. Sorbitol is a non-medicinal ingredient in Irinotecan Hydrochloride Injection USP.
- you are taking medicine to treat a fungal infection, such as ketoconazole, fluconazole, itraconazole.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Irinotecan Hydrochloride Injection USP. Talk about any health conditions or problems you may have, including if you:

- have low blood cell counts due to a decreased ability of the bone marrow to produce blood cells.
- have liver or lung problems.
- have heart disease, have had a recent heart attack or have an irregular heartbeat.
- are taking other drugs (including laxatives, diuretics/fluid pills) or have been previously treated with Irinotecan Hydrochloride Injection USP or other chemotherapy drugs.
- have diarrhea, constipation, or trouble eating and drinking.
- have colitis (bowel inflammation) / ileus (lack of bowel movement).
- are undergoing or have previously undergone radiation treatment.
- have diabetes.

Other warnings you should know about:

Serious Side Effects: Irinotecan Hydrochloride Injection USP can cause the following serious side effects:

- **Diarrhea:** Diarrhea is a common side effect of the chemotherapy you are receiving. Irinotecan Hydrochloride Injection USP can cause both an early and late form of diarrhea. Early diarrhea occurs during or shortly after you have been given Irinotecan Hydrochloride Injection USP. Late diarrhea occurs more than 24 hours and can start up to several days after you have been given Irinotecan Hydrochloride Injection USP. While both forms can be severe, late diarrhea can become severe, quite quickly, and can result in loss of body fluid requiring hospitalization or lead to infection. For this reason, it is important that you pay careful attention to each bowel movement and use the medications provided by your healthcare professional to control diarrhea symptoms.

You have diarrhea if your stools are soft, loose or watery, increased in number or it is hard to control your bowel due to urgency to go to the toilet. Loperamide is a medicine to help control the severity of diarrhea. You should begin to take loperamide immediately at the earliest sign of a loose stool or the earliest onset of bowel movements more frequent than you would normally expect. However, never take loperamide to prevent diarrhea.

You should take the loperamide as follows: 4 mg (2 tablets) at the first onset of loose stools or diarrhea and then 2 mg (1 tablet) every 2 hours until you have been without diarrhea for at least 12 hours. During the night, you may take 4 mg (2 tablets) of loperamide every 4 hours. In

addition, you should try to drink lots of clear liquids (e.g. water, apple juice, broth, sports drinks, non-fizzy soft drinks) in order to prevent dehydration. You should not use loperamide for more than 48 consecutive hours.

Diarrhea associated with nausea and/or vomiting: Vomiting can prevent you from replacing fluids lost due to diarrhea. As a result, you could be in danger of serious dehydration that could result in severe complications or death. If you have diarrhea and vomiting together for more than 12 hours, talk to your healthcare professional right away.

Diarrhea in association with fever: The fever may be a sign of infection that could result in severe complications or death. If you have a diarrhea and a fever, talk to your healthcare professional right away.

Diarrhea lasting for more than 24 hours (while using loperamide): Prolonged diarrhea, even without nausea, vomiting or fever, can put you at risk for dehydration or infection. If you have diarrhea lasting for 24 hours, talk to your healthcare professional right away.

- **Nausea and Vomiting:** The amount of nausea and vomiting varies widely from person to person. Some people have mild nausea and vomiting, while others may have severe nausea and vomiting for a short time after treatment. Nausea and vomiting may start right after a chemotherapy treatment or several hours later and may last several days. Vomiting can become quite severe, and you can lose body fluid which can cause you to become dehydrated. Vomiting can also make it difficult for you to take medications (such as loperamide for diarrhea). Your healthcare professional can give you medicine to prevent nausea or reduce its severity. Here are some tips that may help reduce nausea.
 - Eat small meals or snacks throughout the day instead of 2 or 3 large meals.
 - Eat foods that are cold or at room temperature.
 - Cut out foods that are fried, spicy, fatty or sweet.
 - Stay away from odours that may bother you such as cooking smells, cigarette smoke, car exhaust or perfume.
 - Sit upright in a chair after eating – don't lie flat for at least 2 hours.
 - Wear loose-fitting clothes, especially around the waist.
 - You can also try drinking clear fluids (water, diluted soft drinks, apple juice, and broth) or sucking on popsicles, ice chips, mints, or sour candy (but avoid sour candy if you have mouth sores).
 - Eat something light a few hours before your chemotherapy treatment.

If these suggestions and the medications you are taking do not work, or if nausea and vomiting become so severe you cannot take anti-nausea or other medications, talk to your healthcare professional right away or go to your nearest emergency room.

- **Gut Problems (inflammation and blockage):** Cases of colitis (inflammation of the intestines) and ileus (lack of bowel movements) have been reported in people taking Irinotecan Hydrochloride Injection USP.
- **Infection:** A week or two after a chemotherapy cycle, your white blood cell count may be low. This is the most dangerous time for getting an infection. White blood cells defend your body

against infections. When there are very few white blood cells, there may not be enough to fight off an infection. It's important to know the signs of infection so that you can get treatment before the infection becomes serious. The signs of infection include:

- fever over 38°C (100°F)
- chills or sweating
- sore throat or coughing
- redness or swelling around a cut, wound or a catheter site
- a burning feeling when you urinate
- unusual vaginal itching or discharge

Talk to your healthcare professional right away if you have any signs of infection.

Your healthcare professional may prescribe oral antibiotics to help prevent infection during chemotherapy. They may also give you a medicine to help increase the number of your white blood cells. The following tips can help you prevent infections:

- Wash your hands often. Use lotion afterwards to prevent your skin from becoming dry and cracked.
 - Bathe or shower every 1 to 2 days.
 - Be careful not to cut yourself when you use a knife, scissors, razor or other sharp objects.
 - Stay away from people who are sick.
 - Have someone else clean cat litter boxes, birdcages or fish tanks.
 - Eat well-balanced meals.
- **Heart Attacks, Strokes or Blood Clots:** These types of serious heart and blood problems have happened in people taking Irinotecan Hydrochloride Injection USP. They may happen both in patients with known risk factors for heart problems or blood clots and in patients without known risk factors for these conditions. These conditions can be life-threatening or fatal. The signs of heart attacks, strokes or blood clot include:
 - Worsening of pre-existing chest pain.
 - New onset of chest pains and/or shortness of breath.
 - Sudden loss of vision, difficulty speaking, or loss of muscular function or loss of sensation on one side of your body.
 - Swelling in one of your legs (this may be evidence of a blood clot in the legs that could put you at risk for more serious complications).
 - If you have a central venous catheter and you develop swelling in the arm or neck on the side of the catheter (possible evidence of a blood clot).

Get immediate medical help if you experience any of these symptoms.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Anemia (low levels of red blood cells): Chemotherapy medicines affect the bone marrow, which is where red blood cells are formed. Red blood cells carry oxygen to the muscles and other tissues in your body. When there are too few red blood cells, your muscles, and other body tissues can't get enough oxygen to do their work, and you feel exhausted. If your red blood cell count drops very low, you may

also feel weak or dizzy, or may have shortness of breath. These are all symptoms of anemia. If you have these symptoms, tell your healthcare professional.

Fatigue: Feeling tired - or fatigued - is one of the most common side effects of chemotherapy. Many other factors such as stress, diet, sleeping patterns, and your age can also cause fatigue. For some, fatigue may start to improve 2 to 3 months after you complete your chemotherapy treatments. Here's how you can help reduce fatigue.

- Plan your activities. Allow rest between periods of activity.
- List all of the things you have to do, and number them in order of importance. Only do the things on your list that must get done. Leave the other tasks for another day.
- Ask family and friends to help you with driving, house-work or other tasks. For example, ask your friend to pick up a few things for you the next time they go to the supermarket.
- Eat a well-balanced diet.
- Do light exercise regularly.

Hair loss: Hair loss is common in chemotherapy. The hair loss is temporary, and your hair usually starts to grow back within 2 or 3 months after you've finished your treatments. Many survivors suggest getting a wig before you start chemotherapy treatment. That way, your stylist can match your current hair color and set it in the same style. While wigs can be expensive, there are organizations such as The Canadian Cancer Society that provide wigs free of charge. In addition to wigs, some people like to wear stylish hats, scarves, or turbans to cover their head.

Speech Disorders: Speech disorders such as difficulty speaking, stuttering and/or slurred speech, sometimes occurring with tingling or numbness of the mouth or tongue, have been seen during or immediately following Irinotecan Hydrochloride Injection USP treatment. In most cases, these symptoms improved within minutes to hours after finishing Irinotecan Hydrochloride Injection USP treatment. If you experience any difficulty speaking, change in voice and/or tingling or numbness of the mouth or tongue during or after your treatment with Irinotecan Hydrochloride Injection USP, tell your healthcare professional right away.

Female Patients:

- You should not get pregnant while taking Irinotecan Hydrochloride Injection USP and for 6 months after your last dose. It may harm your unborn baby or make you lose the pregnancy. If you get pregnant while taking Irinotecan Hydrochloride Injection USP, tell your healthcare professional right away.
- If you are a woman who is able to get pregnant, a pregnancy test should be done: before you start to take Irinotecan Hydrochloride Injection USP; regularly while you are taking it; and one month after taking your last dose.
- You must use an effective method of birth control while you are taking Irinotecan Hydrochloride Injection USP and for 6 months after your last dose.
- Irinotecan Hydrochloride Injection USP may pass into breast milk. Do not breastfeed while you are taking Irinotecan Hydrochloride Injection USP and for 1 week after your last dose. If you are planning to breastfeed, talk to your healthcare professional about other ways to feed your baby while you are taking Irinotecan Hydrochloride Injection USP.

Male Patients:

- You must not father a child while you are taking Irinotecan Hydrochloride Injection USP and for

3 months after your last dose.

- Use a condom when having sexual intercourse with your female partner, even if she is pregnant. You must continue to use condoms while you are taking Irinotecan Hydrochloride Injection USP, and for 3 months after your last dose.
- Your female partner must also use an effective method of birth control while you are taking Irinotecan Hydrochloride Injection USP and for 3 months after your last dose. If your female partner gets pregnant while you are taking Irinotecan Hydrochloride Injection USP, talk to your healthcare professional right away.
- Do not donate sperm while taking Irinotecan Hydrochloride Injection USP and for 3 months after your last dose.

Blood Tests and Monitoring: Before you use Irinotecan Hydrochloride Injection USP, talk to your healthcare professional to understand what kind of tests will be needed before, during and after treatment. It is very important to go to all the medical appointments that your healthcare professional has scheduled for you. Your healthcare professional will order blood tests to check your blood count (white blood cells, red blood cells, and platelets), heart and liver function, X-rays or other tests. These tests will help your healthcare professional determine your condition before you start taking Irinotecan Hydrochloride Injection USP and while you are taking it.

After you have completed all your chemotherapy treatments, your healthcare professional will check you regularly to make sure the cancer has not returned.

Working During Irinotecan Hydrochloride Injection USP Treatment: Some people work full time, while others work part time or wait until their chemotherapy treatments are finished before returning to work. It depends on the type of job you have and the side effects you experience.

Driving and Using Machines: Many of the side effects of Irinotecan Hydrochloride Injection USP such as fatigue, dizziness, and changes in vision can affect your ability to drive and operate machinery. Give yourself time after you have been given Irinotecan Hydrochloride Injection USP to see how you feel before driving a vehicle or using machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Irinotecan Hydrochloride Injection USP:

- antibiotics used to treat bacterial infections, such as ciprofloxacin, norfloxacin, clarithromycin, erythromycin, azithromycin, rifampin
- medicines used to treat fungal infections, such as ketoconazole, fluconazole, itraconazole
- medicines used to treat heart problems called “calcium channel blockers”, such as verapamil, diltiazem, nifedipine
- medicines used to prevent seizures, such as phenytoin, phenobarbital, carbamazepine
- atazanavir sulfate, a medicine used to treat HIV infection
- cimetidine, a medicine used to treat ulcers
- dexamethasone, a medicine used to treat certain types of swelling or allergies
- St. John’s Wort, an herbal medicine used to treat depression
- grapefruit juice. Do not drink grapefruit juice, eat grapefruit or consume any products that contain grapefruit or grapefruit juice while you are taking Irinotecan Hydrochloride Injection USP.

How to take Irinotecan Hydrochloride Injection USP:

Usual dose:

Your healthcare professional will decide on your dose and the length of your treatment based on your treatment goals, the medicines you receive, and how your body responds to those medicines.

Chemotherapy is usually given in cycles that include rest periods between treatments. The rest periods give your body a chance to build healthy new cells and regain your strength before your next treatment. You may receive one dose of Irinotecan Hydrochloride Injection USP every week for four weeks (on Day 1, 8, 15, 22 of the cycle) followed by a 2-week rest. Or, you may receive Irinotecan Hydrochloride Injection USP once every 2 weeks (on Day 1, 15, 29 of the cycle) followed by a 1-week rest. Or, you may receive Irinotecan Hydrochloride Injection USP once every 3 weeks. Your treatment cycle will depend on your medical condition and the other chemotherapy medicines you are getting. Do not skip doses or make changes in your treatment on your own.

How is Irinotecan Hydrochloride Injection USP given?

You will be given Irinotecan Hydrochloride Injection USP through a vein in the arm (“intravenously” or “IV”), usually in the hospital, outpatient department or clinic. To administer Irinotecan Hydrochloride Injection USP, your healthcare professional will insert a thin needle or plastic tube (IV) in a vein which allows fluid to drip into your vein from a plastic bag.

If you are getting many treatments over several weeks or months, for your convenience, your healthcare professional may insert a catheter (thin tube) or port into a large vein in your body that is placed there as long as it is needed. Medicines get injected through the catheter or port rather than directly into a vein.

It usually takes about 90 minutes to inject Irinotecan Hydrochloride Injection USP. However, you may get other medicines before or after Irinotecan Hydrochloride Injection USP, so your entire treatment may last longer. If you are getting a medicine to prevent nausea, you will probably take that medicine first. Then you will get the rest of your IV medicines, including Irinotecan Hydrochloride Injection USP, one at a time.

Overdose:

If you think you, or a person you are caring for, have been given too much Irinotecan Hydrochloride Injection USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Irinotecan Hydrochloride Injection USP?

These are not all the possible side effects you may have when taking Irinotecan Hydrochloride Injection USP. If you experience any side effects not listed here, tell your healthcare professional.

Chemotherapy medicines work by killing the fastest growing cells in the body, which include cancer cells and some normal cells. Normal cells that grow very rapidly are in your bone marrow, lining of the mouth, stomach, and hair follicles. Since these fast-growing cells can be affected by chemotherapy medicines, this can lead to side effects such as diarrhea. The most common side effects are: low white cell count (increasing the risk of infection), low red cell count (anemia), nausea and vomiting, and hair loss. These side effects usually disappear after treatment ends. Before your next cycle of

chemotherapy, your white blood cells count normally increases and new cells grow back. After your chemotherapy is completely finished, your hair will begin to grow back.

Tell your healthcare professional right away if you feel any of the following symptoms during your treatment or a few hours after treatment:

- Runny nose, watery eyes, more saliva in your mouth.
- Diarrhea and/or stomach cramps.
- Nausea or vomiting.
- Sweating.
- Flushing (your face and neck may feel hot and look red).
- Visual disturbances.
- Pain or burning during the injection.

Don't wait until your treatment is finished. Your healthcare professional may give you a medicine to relieve these symptoms. You may also get medicine before or after future treatments to prevent these symptoms.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Diarrhea, Nausea and Vomiting: <ul style="list-style-type: none"> • Diarrhea for the first time during your treatment • Diarrhea with nausea and/or vomiting • Diarrhea lasting more than 24 hours • Diarrhea with fever Vomiting for more than 12 hours		√	
Dehydration: light-headedness, dizziness, or fainting; dry, flushed or pale skin; irritability or confusion, urinating less often		√	
Infections: fever, chills or sweating, sore throat or coughing, redness or swelling around cut, wound or a catheter site, burning feeling when you urinate		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Gut problems (inflammation, blockage): black or bloody stool, abdominal pain, inability to pass gas or stool		√	
Low levels of blood platelets: bruising, small red haemorrhages into the skin, failure of cuts to stop bleeding or blood in stool		√	
Heart Attack: chest pain, shortness of breath, and sensation of fullness/ heaviness in the chest		√	
Stroke: sudden loss of vision, difficulty speaking, loss of muscular function or loss of sensation on one side of your body		√	
Blood Clot: swelling, warmth and redness in a vein of one of your legs, arm or neck		√	
RARE			
Progressively increasing shortness of breath		√	
VERY RARE			
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Irinotecan Hydrochloride Injection USP will be stored by your healthcare professional.

If you want more information about Irinotecan Hydrochloride Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca or by calling 1-800-463-6001.

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