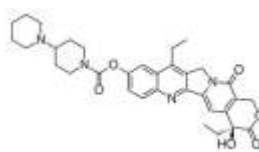


RX IRINOTECAN

(This medication is used to treat cancer of the colon and rectum.)



USES

This medication is used to treat cancer of the colon and rectum. OTHER This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional. This drug may also be used to treat cancer of the lungs.

HOW TO USE

This medication is given by injection into a vein by a health care professional. Learn all preparation and usage instructions for this product. The medication should appear pale yellow and clear. Before using this product, check it visually for particles or discoloration. If either is present, do not use the liquid. Follow all instructions for proper dilution with the correct IV fluid. If you have questions about the use of this medication, consult the doctor or pharmacist. The dosage is based on your medical condition, body size, and response to treatment. Do not increase your dose or use this medication more often than prescribed. Your condition will not improve any faster, and the risk of serious side effects may be increased. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist. If this medication comes into contact with your skin, wash the skin immediately and completely with soap and water. If this medication gets into your eyes, mouth, or nose, flush completely with plenty of water. Consult your doctor for more details.

SIDE EFFECTS

See also Warning section. Nausea, vomiting, loss of appetite, constipation, cough, drowsiness, mouth sores, weakness, or trouble sleeping may occur. Nausea and vomiting can be severe. In some cases, your doctor may prescribe medication to prevent or relieve nausea and vomiting. Eating several small meals, not eating before treatment, or limiting activity may help lessen some of these effects. If these effects persist or worsen, or if you are unable to drink/eat because of nausea/vomiting, tell your doctor or pharmacist promptly. Temporary hair loss may occur. Normal hair growth should return after treatment has ended. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: pain/redness/swelling at the injection site or arms/legs, numbness/tingling/burning of arms/legs, black/bloody stools, shortness of breath. Tell your doctor immediately if any of these rare but very serious side effects occur: change in the amount of urine. Seek immediate medical attention if any of these unlikely but serious side effects occur: chest pain, weakness on one side of the body, slurred speech, confusion, trouble breathing. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. Irinotecan can commonly cause a mild rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe allergic reaction. Therefore, seek immediate medical attention if you develop any rash. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before using irinotecan, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: bowel blockage (e.g., paralytic ileus), certain genetic metabolism disorder (fructose intolerance). Before using this drug, tell your doctor your medical history, including: radiation treatments, blood/bone marrow disorders (e.g., low platelet/neutrophil/red blood cell levels), diabetes, liver disease, kidney disease, lung disease. Before having surgery, tell your doctor or dentist that you are using this medication. This drug may make you dizzy or drowsy or cause blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages. To avoid dizziness and lightheadedness when rising from a sitting or lying position, get up slowly. Do not have immunizations/vaccinations without the consent of your doctor, and avoid contact with people who have recently received oral polio vaccine or flu vaccine inhaled through the nose. To lower your risk of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports. Wash your hands well to prevent the spread of infections. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug, especially diarrhea. This medication is not recommended for use during pregnancy. It may harm an unborn baby. Therefore, it is important to prevent pregnancy while using this medication. Consult your doctor for more details and to discuss using at least 2 reliable forms of birth control (e.g., condoms, birth control pills) while using this medication. If you become pregnant or think you may be pregnant, tell your doctor immediately. It is not known whether this drug passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or

change the dosage of any medicine before checking with your doctor or pharmacist first. This drug should not be used with the following medications because very serious interactions may occur: atazanavir. Avoid taking St. John's wort within 2 weeks before or during treatment with this medication, and avoid taking ketoconazole within 1 week before or during treatment with this medication. If you are currently using any of these medications listed above, tell your doctor or pharmacist before starting irinotecan. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: drugs affecting liver enzymes that remove irinotecan from your body (such as rifamycins including rifabutin, certain anti-seizure medicines including carbamazepine/phenytoin/phenobarbital), laxatives, "water pills"/diuretics (e.g., furosemide). Avoid eating foods or taking products containing turmeric (curcumin) while being treated with irinotecan. It may decrease this medication's effects. Consult your doctor or pharmacist for more details. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: signs of infection (e.g., persistent sore throat, fever), severe diarrhea.

MISSED DOSE

For the best possible benefit, it is important to receive each scheduled dose of this medication as directed. If you miss a dose, contact your doctor to establish a new dosing schedule. Do not double the dose to catch up.

STORAGE

Store unopened vials at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Avoid freezing. Store the diluted medication at room temperature between 59-86 degrees F (15-30 degrees C), and use within 6 hours. Consult with the pharmacist for additional storage information. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product. MEDICAL ALERT: Your condition can cause complications in a medical emergency. For information about enrolling in MedicAlert, call 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).

WARNING: You will be closely monitored (e.g., blood tests) by your doctor while using this medication. Keep all medical and laboratory appointments.

Irinotecan may cause severe diarrhea, which can occur during or right after you receive this medication and/or more than 24 hours afterward. If the diarrhea starts immediately, you may also have other side effects such as runny nose, increased saliva, watery eyes, sweating, stomach cramps, or flushing. If the diarrhea starts later, it could be a different type that may be persistent and can cause serious (possibly fatal) loss of too much body water (dehydration), mineral imbalance, or serious infection (sepsis). Tell your doctor immediately if you have diarrhea and/or any of the symptoms that occur with the early form of diarrhea. Also tell your doctor if you have stomach/abdominal pain, extreme thirst, very dry mouth, muscle cramps/weakness, fast/slow/irregular heartbeat, fainting, dizziness, lightheadedness, or signs of infection (e.g., fever, persistent sore throat). Your doctor should prescribe other medications to treat the diarrhea and other symptoms.

This medication may cause very serious (possibly fatal) blood disorders (decreased bone marrow function leading to low number of blood cells such as white cells, red cells, and platelets). This effect can decrease your body's ability to fight an infection, cause your body to bruise or bleed easier, or cause anemia. Tell your doctor immediately if you develop any of the following: signs of infection (fever, persistent sore throat), easy bruising/bleeding, unusual tiredness, fast/pounding heartbeat.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

Taj DRUG WORLD

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