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





Active Pharmaceuticals Ingredients Manufacturers

# Taj Pharmaceuticals Ltd. Irinotecan Hcl CAS No. : 100286-90-6

#### Identifiers

Molecular Formula C33H38N4O6.HCl Molecular Weight 623.15 CAS Registry Number 100286-90-6 Melting point 250-256 °C (dec.)

ATC code L01XX19 PubChem 3750 DrugBank APRD00579

## Chemical data

Formula C33H38N4O6 Mol. mass 586.678 g/mol 677.185 g/mol (hydrochloride)

#### Pharmacokinetic data

Bioavailability NA Metabolism Hepatic glucuronidation Half life 6 to 12 hours Excretion Biliary and renal

# USES

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

# 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.

# **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



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#### DOSAGE

\* as a drip (infusion) through a fine tube (cannula) inserted into a vein

\* through a central line, which is inserted under the skin into a vein near the collarbone, or into a PICC line, which is inserted into a vein in the crook of your arm.

Chemotherapy is usually given as a course of several sessions (or cycles) of treatment over a few months. The length of your treatment and the number of cycles you have will depend on the type of cancer for which you are being treated. Irinotecan is commonly given alongside other chemotherapy drugs as part of a combination regimen. Your nurse or doctor will discuss your treatment plan with you.

Irinotecan is given as an injection through a needle placed into a vein. You will receive this injection in a clinic or hospital setting. The medicine must be given slowly through an IV infusion, and can take up to 90 minutes to complete. The irinotecan injection is usually followed by infusions with other cancer medications. These combination chemotherapy treatments are usually given at weekly intervals for several weeks.

Before starting your irinotecan injection, you may be given medications to help prevent nausea, vomiting, diarrhea, and other side effects. You may also need to use some of these medications for at least a day after your irinotecan injection.

Irinotecan can cause severe diarrhea, which can be life-threatening if it leads to dehydration. Diarrhea can occur soon after your injection or more than 24 hours later.

Your doctor may recommend you have an anti-diarrhea medicine such as loperamide (Imodium) available at all times while you are receiving irinotecan. The anti-diarrhea medication is usually taken at the first sign of loose or frequent bowel movements.

#### **SIDE EFFECTS**

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Call your doctor at once if you have any of these serious side effects:

\*pale skin, easy bruising or bleeding, unusual weakness;

\*loose stools, watery diarrhea;

\*bloody or black stools;

\*runny nose, watery eyes, increased sweating, stomach cramps, and warmth, tingling, or redness under your skin;

\*fever, chills, body aches, flu symptoms;

\*white patches or sores inside your mouth or on your lips;

\*sudden numbness or weakness, headache, confusion, problems with vision, speech, or balance;

\*chest pain, pain or swelling in one or both legs;

\*swelling or irritation where the IV needle is placed;

\*nausea or vomiting that keeps you from drinking enough fluids; or

\*signs of dehydration, such as dry mouth, increased thirst, drowsiness, feeling light-headed, or fainting.

Less serious side effects may be more likely to occur, such as:

\*loss of appetite, constipation;

\*dizziness;

\*redness or peeling of the skin on your hands and feet;

\*cough,

\*temporary hair loss.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

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## PRECAUTIONS

Do not use a laxative or stool softener during treatment with irinotecan. These products can worsen diarrhea that may be caused by irinotecan. Avoid being near people who have colds, the flu, or other contagious illnesses. Contact your doctor at once if you develop signs of infection.

Do not receive a "live" vaccine while you are being treated with irinotecan, and avoid coming into contact with anyone who has recently received a live vaccine. There is a chance that the virus could be passed on to you. Avoid getting this medicine on your skin. If this happens, wash the area thoroughly with soap and warm water. Irinotecan can cause side effects that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert.



#### **DRUG DESCRIPTION**

Irinotecan is a chemotherapy drug that is given as a treatment for some types of cancer. It is most commonly used to treat bowel cancer. This information describes irinotecan, how it is given and some of its possible side effects. It should ideally be read with our general information about chemotherapy and about bowel cancer.

Irinotecan is a cancer medication that interferes with the growth of cancer cells and slows their growth and spread in the body.

Irinotecan is used to treat cancers of the colon and rectum. It is usually given with other cancer medicines in a combination chemotherapy.

Irinotecan may also be used for purposes other than those listed in this medication guide.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009



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