Package leaflet: Information for the patient
Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
Irinotecan Hydrochloride Trihydrate
PACKAGE LEAFLET: INFORMATION FOR THE USER

Rx Irinotecan Hydrochloride Injection, USP

Package Leaflet: Information For The User
Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
irinotecan hydrochloride trihydrate
The name of your medicine is 'Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for
Infusion' but in the rest of the leaflet it will be called "Irinotecan Injection".
Read all of this leaflet carefully before you start using this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even
if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet,
please tell your doctor.

In this leaflet:

1. What Irinotecan Injection is and what it is used for
2. What you need to know before you are given Irinotecan Injection
3. How you will be given Irinotecan Injection
4. Possible side effects
5. How to store Irinotecan Injection
6. Contents of the pack and other information

1. What Irinotecan Injection is and what it is used for

Irinotecan belongs to a group of medicines called cytostatics (anti-cancer medicines). Irinotecan is
used for the treatment of advanced cancer of the colon and rectum in adults, either in a combination
with other medicines or alone.
Your doctor may use a combination of Irinotecan with 5-fluorouracil/folinic acid (5FU/FA) and
bevacizumab to treat your cancer of the large intestine (colon or rectum).
Your doctor may use a combination of Irinotecan with capecitabine with or without bevacizumab to
treat your cancer of the colon and rectum.
Your doctor may use a combination of Irinotecan with cetuximab to treat a particular type of cancer
of the large intestine (KRAS wild-type) which expresses a protein called EGFR.

2. What you need to know before you are given Irinotecan Injection

You should not be given Irinotecan Injection if you
are allergic to Irinotecan Injection or any of the other ingredients of this medicine (listed in
section 6)
have or have had chronic inflammatory bowel disease or bowel obstruction

are breast feeding
have severe liver disease
have severe bone marrow failure
are in poor general health (evaluated by an international standard)
are using the natural remedy St John's Wort (hypericum perforatum)

Warnings and precautions
Special care is needed in elderly patients.
As Irinotecan Injection is an anti-cancer medicine it will be administered to you in a special unit and
under the supervision of a doctor qualified in the use of anti cancer medicines. The unit's personnel
will explain to you what you need to take special care of during and after the treatment. This leaflet
helps you to remember that.
Before treatment with Irinotecan Injectiontell your doctor if any of the following apply to you:
You have liver problems or jaundice
You have kidney problems
You have asthma
You have ever received radiation therapy
You experienced severe diarrhoea or fever after being treated with Irinotecan Injection before.
You have heart problems
You smoke, have high blood pressure or high cholesterol as these can increase the risk of heart
problems during treatment with Irinotecan InjectionYou have had or are due to have any
vaccinations
You are taking any other medicines. Please see the section below "Other medicines and
irinotecan".
1) The first 24 hours after administration of Irinotecan Injection
During administration of Irinotecan Injection (30 – 90 min.) and shortly after administration you may
experience some of the following symptoms:
Diarrhoea
Watering eyes
Sweating
Visual disturbance
Abdominal pain
Excessive mouth watering
The medical term for these symptoms is acute cholinergic syndrome, which can be treated (with
atropine). If you have any of these symptoms immediately tell your doctor who will give you any
treatment necessary.
2) From the day after treatment with Irinotecan Injectionuntil next treatment.
During this period you may experience various symptoms, which may be serious and require
immediate treatment and close supervision.
Diarrhoea
If your diarrhoea starts more than 24 hours after administration of Irinotecan Injection ("delayed
diarrhoea") it may be serious. It is often seen about 5 days after administration. The diarrhoea should
be treated immediately and kept under close supervision. Immediately after the first liquid stool do the
following:
1. Take any anti-diarrhoeal treatment that the doctor has given you, exactly as he/she has told you.
The treatment may not be changed without consulting the doctor. Recommended anti diarrhoeal
treatment is loperamide (4 mg for the first intake and then 2 mg every 2 hours, also during the
night). This should be continued for at least 12 hours after the last liquid stool. The
recommended dosage of loperamide may not be taken for more than 48 hours.

2. Drink large amounts of water and rehydration fluids immediately (i.e. water, soda water, fizzy drink, soup or oral rehydration therapy).
3. Immediately inform your doctor who is supervising the treatment and tell him/her about the
diarrhoea. If you are not able to reach the doctor contact the unit at the hospital supervising the
Irinotecan Injection treatment. It is very important that they are aware of the diarrhoea
You must immediately tell the doctor, or the unit supervising the treatment, if
You have nausea, vomiting or any fever as well as diarrhoea
You still have diarrhoea 48 hours after starting the diarrhoea treatment
Note: Do not take any treatment for diarrhoea other than that given to you by your doctor and the
fluids described above. Follow the doctor's instruction. The anti-diarrhoeal treatment should not be
used to prevent a further episode of diarrhoea even though you have experienced delayed diarrhoea at
previous cycles.
Fever
If the body temperature increases over 38 C it may be a sign of infection, especially if you also have
diarrhoea. If you have any fever (over 38 C) contact your doctor or the unit immediately so that they
can give you any treatment necessary.
Nausea and vomiting
If you have nausea and/or vomiting contact your doctor or the unit immediately.
Neutropenia
Irinotecan Injection may cause a decrease in the number of some of your white blood cells, which
play an important role in fighting infections. This is called neutropenia. Neutropenia is often seen
during treatment with Irinotecan Injection and is reversible. Your doctor should arrange for you to
have regular blood tests to monitor these white blood cells. Neutropenia is serious and should be
treated immediately and carefully monitored.
Breathing difficulties
If you have any breathing difficulties contact your doctor immediately.
Impaired liver function
Before treatment with Irinotecan Injection is started and before every following treatment cycle the
liver function should be monitored (by blood tests).
Other medicines and irinotecan
Please tell your doctor if you are taking or have recently taken any other medicines, including
medicines obtained without a prescription. This includes herbal medicines, strong vitamins and
minerals.
If you receive Irinotecan Injection in combination with capecitabine, cetuximab or bevacizumab,
please make sure that you also read the patient information leaflet for each medicine.
Some medicines may alter the effects of Irinotecan Injection e.g. ketoconazole (for the treatment of
fungal infections), rifampicin (for the treatment of tuberculosis), warfarin (an anticoagulant used to
thin the blood), atazanavir (used to treat HIV), ciclosporin or tacrolimus (used to dampen down your
body's immune system) and some medicines for the treatment of epilepsy (carbamazepine,
phenobarbital and phenytoin).
The herbal medicine St John's Wort (hypericum perforatum) may not be used concurrently with
Irinotecan Injection and not between treatments, as it may decrease the effect of Irinotecan Injection.
If you require an operation, please tell your doctor or anesthetist that you are being treated with
irinotecan,as it may alter the effect of some medicines used during surgery.
Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a
baby, ask your doctor or pharmacist for advice before taking this medicine. Irinotecan Injection
must not be used during pregnancy. Irinotecan Injection can cause birth defects.
Women of child-bearing age should avoid becoming pregnant. Contraceptive measures must be taken
by both male and female patients during and for at least three months (by males) and one month (by
females) after cessation of therapy. Still, if you become pregnant during this period you must
immediately inform your doctor.
Breast feeding must be discontinued for the duration of Irinotecan Injectiontherapy.
Ask your doctor for advice before taking any medicine.
Driving and using machines
In some cases Irinotecan Injection may cause side effects, which affect the ability to drive and use
tools and machines. Contact your doctor if you are unsure.
During the first 24 hours after administration of Irinotecan Injection you may feel dizzy or have visual
disturbances. If this happens to you do not drive or use any tools or machines.
Important information about some of the ingredients of Irinotecan Injection
Irinotecan Injection contains sorbitol. If you suffer from intolerance to some sugars, tell your doctor
before you are given this medicinal product.
This medicinal product contains less than 1 mmol sodium per dose, i.e. essentially 'sodium-free'.

3. How you will be given Irinotecan Injection

Irinotecan Injection will be given as an infusion into your veins over a period of 30 to 90 minutes.
The amount of infusion you are given will depend on your age, size and general medical condition. It
will also depend on any other treatment you may have received for your cancer. Your doctor will
calculate your body surface area in square meters (m2).
If you have previously been treated with 5-fluorouracil you will normally be treated with
Irinotecan Injection alone starting with a dose of 350 mg/m2 every 3 weeks.

If you have not had previous chemotherapy you will normally receive 180 mg/m2 Irinotecan
Injection every two weeks. This will be followed by folinic acid and 5-fluorouracil.

If you are treated with irinotecan in combination with cetuximab you will normally receive the
same dose of irinotecan as administered in the last cycles of the prior irinotecan containing
regimen. Irinotecan Injection must not be administered less than 1 hour after the end of the
cetuximab infusion.
These dosages may be adjusted by your doctor depending on your condition and any side effects you
may have.

If you receive more Irinotecan Injection than you should
It is unlikely that you will be given too much Irinotecan Injection. However in the event that this
occurs you may have severe blood disorders and diarrhoea. Maximum supportive care should be taken
to prevent dehydration due to diarrhoea and to treat any infectious complications. You should talk to
the doctor administering your medicine.
If you miss a dose of Irinotecan Injection
It is very important to receive all scheduled doses. If you miss a dose, contact your doctor promptly.

4. Possible side effects

Like all medicines, Irinotecan Injection can cause side effects, although not everybody gets them.
Your doctor will discuss these side effects with you and explain the risks and benefits of your
treatment. Some of these side effects must be treated immediately.
See also information in section "Warnings and precautions"
If you experience any of the following side effects after you have been given your medicine, tell your
doctor immediately. If you are not in hospital, you MUST GO straight away.
Allergic reactions. If you have wheeziness, difficulty in breathing, swelling, rash or itching
(especially affecting the whole body) contact your doctor or nurse immediately.
Severe allergic reactions (anaphylactic/anaphylactoid reactions) may occur most often in the
minutes following injection of the product: skin rash including red itchy skin, swelling of the
hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or
breathing) and you may feel you are going to faint.
Very common (may affect more than 1 in 10 people)
Blood disorder: neutropenia (decreased number of some white blood cells), thrombocytopenia
(decreased number of blood platelets), anaemia
Delayed diarrhoea
Nausea and vomiting
Hair loss (the hair grows again after end of treatment)
In combination therapy transient increase in the levels of liver enzymes or bilirubin
Common (may affect up to 1 in 10 people)
Acute cholinergic syndrome: the main symptoms are early diarrhoea and other symptoms such
as abdominal pain; red, sore, itching and weeping eyes (conjunctivitis); running nose (rhinitis);
low blood pressure; widening of the blood vessels; sweating, chills; a feeling of general
discomfort and illness, dizziness; visual disturbance, small pupils; watering eyes and increased
salivation, occurring during or within the first 24 hours after the infusion of Irinotecan
Injection.
Fever, infections (including sepsis)
Fever associated with a severe decrease in the number of white blood cells
Dehydration, commonly associated with diarrhoea and/or vomiting.
Constipation
Fatigue
Increased level of liver enzymes and creatinine in the blood.
Uncommon (may affect up to 1 in 100 people)
Allergic reactions. If you have wheeziness, difficulty in breathing, swelling, rash or itching
(especially affecting the whole body) contact your doctor or nurse immediately.
Mild skin reactions; mild reactions at the infusion site
Difficulty breathing
Lung disease (interstitial pulmonary disease)
Intestinal blockage
Abdominal pain and inflammation, causing diarrhoea (a condition known as
pseudomembranous colitis)
Infrequent cases of renal insufficiency, low blood pressure or cardio-circulatory failure have
been observed in patients who experienced episodes of dehydration associated with diarrhoea
and/or vomiting or sepsis.
Rare (may affect up to 1 in 1,000 people)
Severe allergic reactions (anaphylactic/anaphylactoid reactions) may occur most often in the
minutes following injection of the product: skin rash including red itchy skin, swelling of the
hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or
breathing) and you may feel you are going to faint. If this happens you should tell your doctor
immediately
Early effects such as muscular contraction or cramps and numbness (paraesthesia).
Gastrointestinal bleeding and inflammation of the colon including the appendix
Intestinal perforation; anorexia; abdominal pain; inflammation of mucous membranes
Inflammation of pancreas
Increased blood pressure during and following administration.
Decreased levels of potassium and sodium in the blood, mostly related to diarrhoea and
vomiting
Very rare (may affect up to 1 in 10,000 people)
Transient speech disorders
Increase in levels of some digestive enzymes, which break down sugars and fats.
Not known (frequency cannot be estimated from the available data)
Inflammation of the liver with concurrent fat accumulation in liver
If you receive Irinotecan Injection in combination with cetuximab, some of the side effects you may
experience can also be related to this combination. Such side effects may include an acne- like rash.
Therefore, please make sure that you also read the package leaflet for cetuximab.
If you receive Irinotecan Injection in combination with capecitabine, some of the side effects you
may experience can also be related to this combination. Such side effects may include: very common
blood clots, common allergic reactions, heart attack and fever in patients with a low white blood cell
count. Therefore, please make sure that you also read the package leaflet for capecitabine.
If you receive Irinotecan Injection in combination with capecitabine and bevacizumab, some of the
side effects you may experience can also be related to this combination. Such side effects include: low
white blood cell count, blood clots, high blood pressure and heart attack. Therefore, please make sure
that you also read the package leaflet for capecitabine and bevacizumab.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please
tell your doctor or pharmacist.
Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side
effects not listed in this leaflet. You can also report side effects directly via the national reporting
system (see contact details below). By reporting side effects you can help provide more information
on the safety of this medicine.

5. How to store Irinotecan Injection

Keep out of the reach and sight of children.
Do not freeze.
For single use only.
This medicinal product does not require any special temperature storage conditions. Store in the
original package in order to protect from light.
Do not use this medicinal product after the expiry date which is stated on the carton and the vial after
EXP. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to
dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion contains
The active substance is irinotecan hydrochloride trihydrate.
1 ml of concentrate contains 20 mg irinotecan hydrochloride trihydrate equivalent to 17.33 mg
of irinotecan.
One 2 ml vial contains 40 mg irinotecan hydrochloride trihydrate
One 5 ml vial contains 100 mg irinotecan hydrochloride trihydrate
One 15 ml vial contains 300 mg irinotecan hydrochloride trihydrate
One 25 ml vial contains 500 mg irinotecan hydrochloride trihydrate
The other ingredients are sorbitol (E420), lactic acid, sodium hydroxide, hydrochloric acid and
water for injections.
What Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion looks like and
contents of the pack
Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion is a clear, pale yellow
coloured solution.

Pack sizes: 2 ml/ 5 ml/ 15 ml/ 25 ml
Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder

Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
at SURVEY NO.188/1 TO 189/1,190/1 TO 4,
ATHIYAWAD, DABHEL, DAMAN- 396210 (INDIA)

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Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
The following information is intended for medical or healthcare professionals only:
Instructions for use - Cytotoxic
Handling of Irinotecan Injection
As with other antineoplastic agents, caution should be exercised when handling Irinotecan Injection.
Dilution should be carried out under aseptic conditions by trained personnel in a designated area.
Precautions should be taken to avoid contact with the skin and mucous membranes.
Protection instructions for preparation of Irinotecan solution for infusion
1. Protective chamber should be used and protective gloves as well as protective gown should be
worn. If there is no protective chamber available mouth cover and goggles should be used.
2. Opened containers, like injection vials and infusion bottles and used cannulae, syringes,
catheters, tubes, and residuals of cytostatics should be considered as hazardous waste and
undergo disposal according to local guidelines for the handling of HAZARDOUS WASTE.
3. Follow the instructions below in case of spillage:
protective clothing should be worn
broken glass should be collected and placed in the container for HAZARDOUS WASTE.
contaminated surfaces should be flushed properly with copious amount of cold water
the flushed surfaces should then be wiped thoroughly and the materials used for wiping should
be disposed as HAZARDOUS WASTE
4. In the event of Irinotecan Injectioncontact with the skin, the area should be rinsed with plenty
of running water and then washed with soap and water. In case of contact with mucous
membranes, wash the contacted area thoroughly with water. If you have any discomfort, contact
doctor.
5. In case of contact of Irinotecan Injectionwith eyes wash them thoroughly with plenty of water.
Contact an ophthalmologist immediately.
Preparation for the infusion solution
Irinotecan concentrate for solution for infusion is intended for intravenous infusion only after diluting
prior to administration in the recommended diluents, either 0.9 % Sodium chloride solution for
infusion or 5% glucose solution for infusion. Aseptically withdraw the required amount of Irinotecan
concentrate for solution from the vial with a calibrated syringe and inject into a 250 ml infusion bag
or bottle. The infusion should be thoroughly mixed by manual rotation.
The product should be diluted and used immediately after opening.
Irinotecan solution is physically and chemically stable with infusion solutions (0.9% (w/v) sodium
chloride solution and 5% (w/v) glucose solution) for up to 28 days when stored in LDPE or PVC
containers at 5°C or at 25°C and protected from light. When exposed to light. physico-chemical
stability has been demonstrated for up to 3 days.
From a microbiological point of view, the diluted solution should be used immediately. If not used
immediately, in-use storage times and conditions prior to use are the responsibility of the user and
would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution / dilution (etc) has taken
place in controlled and validated aseptic conditions.
If any precipitate is observed in the vials or after reconstitution, the product should be discarded
according to standard procedure for cytotoxic agents.
Irinotecan Injection should not be delivered as an intravenous bolus or an intravenous infusion shorter
than 30 minutes or longer than 90 minutes.
Disposal
All items used for preparation, administration or otherwise coming into contact with Irinotecan
Injection should undergo disposal according to local guidelines for the handling of cytotoxic
compounds.

Rx Irinotecan Hydrochloride Injection, USP

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