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 because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects , talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

In this leaflet:

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. Irinotecan Injection is an anticancer medicine containing the active substance irinotecan hydrochloride, trihydrate. Irinotecan hydrochloride trihydrate interferes with the growth and spread of cancer cells in the body.

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, WHO performance status higher than 2)
- are using the natural remedy St John's Wort (hypericum perforatum)

- if you are to take or have recently taken live attenuated vaccines (vaccines against yellow fever, chicken pox, shingles, measles, mumps, rubella, tuberculosis, rotavirus, influenza) and during the 6 months after stopping chemotherapy

If you receive Irinotecan Injection in combination with other medicines, please make sure that you also read the package leaflet of the other medicines regarding additional contraindications.

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 Injection
- You have had or are due to have any vaccinations
- You are taking any other medicines. Please see the section below **"Other medicines and irinotecan"**
- if you have Gilbert's syndrome, an inherited condition that can cause elevated bilirubin levels and jaundice (yellow skin and eyes).

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

Acute cholinergic syndrome
This medicine may affect part of your nervous system that controls body secretions, leading to what is known as cholinergic syndrome. Symptoms can include runny nose, increased saliva, excess tears in the eyes, sweating, flushing, abdominal cramps, and diarrhoea. Let your doctor or nurse know right away if you notice any of these symptoms, as there are medicines that can help control them.
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. If left untreated, it could lead to dehydration and serious chemical imbalances, which can be life threatening. Your doctor will prescribe medicine

to help prevent or control this side effect. Make sure you get the medicine right away, so that you will have it at home when you need it. 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. Your doctor may give you medicine before your treatment to help prevent nausea and vomiting. Your doctor will likely prescribe anti-nausea medicines that you can take at home. Have these medicines on hand for when you need them. Call your doctor if you are unable to take fluids by mouth due to nausea and vomiting.

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.

Be sure to let your doctor or nurse know right away if you have any signs of infection, such as fever (38°C or higher), chills, pain when passing urine, a new cough, or bringing up sputum. Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

Blood monitoring
Your doctor will likely test your blood before and during your treatment, to check for effects of the medicine on blood counts or on blood chemistry. Based on the test results, you may need medicines to help treat the effects. Your doctor may also need to reduce or delay your next dose of this medicine, or even stop it altogether. Keep all your appointments for doctor visits and lab tests.

This medicine may lower your platelet count in the weeks after it is given, which can increase your risk of bleeding. Speak with your doctor before taking any medicines or supplements that might affect your body's ability to stop bleeding, such as aspirin or aspirin-containing medicines, warfarin, or

vitamin E. Tell your doctor right away if you have unusual bruising, or bleeding such as nosebleeds, bleeding gums when you brush your teeth, or black, tarry stools.

Lung disorders
Rarely, people on this medicine have serious lung problems, Tell your doctor right away if you have new or worsening cough, trouble breathing, and fever. Your doctor may need to stop your treatment to manage this problem.

This medicine may increase your risk of major blood clots in the veins of the legs or lungs, which can travel to other parts of the body such as the lungs or brain. Tell your doctor right away if you notice chest pain, shortness of breath, or swelling, pain, redness, or warmth in an arm or leg.

Chronic intestinal inflammation and/or intestinal blockage
Call your doctor if you have pain in your belly and you cannot move your bowels, especially if you also have bloating and loss of appetite.

Irradiation therapy
If you recently received treatment with pelvic or abdominal radiotherapy, you may be at increased risk of developing bone marrow suppression. Please talk to your doctor before starting the Irinotecan Injection.

Kidney function
Occurrences of kidney dysfunction have been reported.

Cardiac disorders
Inform your doctor if you suffer/suffered from heart disease or if you previously received anti-cancer medicines. Your doctor will monitor you closely and discuss with you how risk factors (for example smoking, high blood pressure and to high fat content) can be reduced.

Vascular disorders
Irinotecan Injection is rarely associated with blood flow disorders (blood clots in the vessels of your legs and lungs) and it may occur rarely in patients with multiple risks factors.

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).

Others
This medicine may cause sores in the mouth or on the lips, often within the first few weeks after starting treatment. This can cause mouth pain, bleeding, or even trouble eating. Your doctor or nurse can suggest ways to reduce this, such as changing the way you eat or how you brush your teeth. If needed, your doctor can prescribe medicine to help with the pain.

Tell your doctor or dentist that you are on this medicine if you are planning to have surgery or any procedure.

If used in combination with other anticancer medicines for your condition please make sure that you also read the leaflets for the other medicine.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

- Medicines used to treat seizure (carbamazepine, phenobarbital, phenytoin and fosphenytoin)
- Medicines used to treat fungal infection (ketoconazole, itraconazole, voriconazole and posaconazole)
- Medicines used to treat bacterial infection (clarithromycine, erythromycin and telithromycine)
- Medicines used to treat tuberculosis (rifampicin and rifabutin) St. John's Wort (a herbal dietary supplement)
- Live attenuated vaccines
- Medicines used to treat HIV (indinavir, ritonavir, amprenavir, fosamprenavir, nelfinavir, atazanavir, and others)
- Medicines used to suppress your body's immune system to prevent transplant rejection (cyclosporine and tacrolimus)
- Medicines used to treat cancer (regorafenib, crizotinib, idelalisib and apalutamide)
- Vitamin K antagonists (common blood thinner such as Warfarin)
- Medicines used to relax muscles used during general anaesthesia and surgery (suxamethonium)
- 5-fluorouracil/folinic acid
- Bevacizumab (a blood vessel growth inhibitor)
- Cetuximab (an EGF receptor inhibitor)

Tell your doctor pharmacist or nurse before being given Irinotecan Injection if you are already having, or have recently had chemotherapy (and radiotherapy).

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.

Don't start or stop taking any medicines while you are on Irinotecan Injection without talking with your doctor first.

This medicine can cause serious diarrhoea. Try to avoid laxatives and stool softeners while taking this medicine.

There may be more medicines that interact with Irinotecan Injection. Check with your doctor, pharmacist or nurse about your other medicines, herbs, and supplements, and whether alcohol can cause problems with this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

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. In pregnant women, treatment with this medicine should be used only if the potential benefit to the mother outweighs the risk to the foetus.

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

No studies have been done, nevertheless, this medicine may pass into breast milk and affect the baby. Breast feeding must be discontinued for the duration of Irinotecan Injectiontherapy.
Ask your doctor for advice before taking any medicine.

Fertility

No studies have been done, nevertheless, this medicine may affect fertility. Talk with your doctor about the possible risk with this medicine and the options that may preserve your ability to have children.

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
This medicine contains 45 mg sorbitol in each ml.
Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.
This medicinal product contains less than 1 mmol sodium per dose, i.e. essentially 'sodium-free'.

3. How you will be given Irinotecan Injection

Always use this medicine exactly as your doctor has told you. Check with your doctor is you are not sure.

Irinotecan Injection will be given to you by healthcare professionals.

Your doctor may recommend a DNA test before your first dose of Irinotecan Injection.

Some people are genetically more likely to have certain side effects from the medicine.

You may be given other medications to prevent nausea, vomiting, diarrhoea, and other side effects while you are receiving Irinotecan Injection. You may need to keep using these medicines for at least a day after your Irinotecan Injection injection.

Tell your care givers if you feel any burning, pain, or swelling around the IV needle when Irinotecan Injection is injected. If the medicine escapes from the vein it can cause tissue damage. If you experience pain or notice redness or swelling at the IV site while you are receiving Irinotecan Injection, alert your healthcare professional immediately.

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 (m^2).

- 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/m^2 every 3 weeks.
- If you have not had previous chemotherapy you will normally receive 180 mg/m^2 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.
- Diarrhoea (see section 2).
- Early diarrhoea: Occurring within 24 hours of receiving this medicine, accompanied by symptoms runny nose, increased salivation, watery eyes, sweating, flushing, abdominal cramping. (This can occur while the medicine is being administered. If so, alert your healthcare professional promptly. Medication can be given to stop and/or lessen this early side effect).
- Late diarrhoea: Occurring greater than 24 hours of receiving this medicine. Because of concerns of dehydration and electrolyte imbalances with diarrhoea it is important to be in contact with health care professionals for monitoring, and for medication and diet modifications advice.

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)
- Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever) caused by bacteria called (Clostridium difficile)
- Blood infection
- Dehydration (due to diarrhoea and vomiting)
- Dizziness, rapid heart beat and pale skin (a condition called hypovolaemia)
- Allergic reaction
- Temporary speech disorders during or shortly after treatment
- Pins and needles
- High blood pressure (during or after infusion)
- Heart problems*
- Lung disease causing wheezing and shortness of breath (see section 2)
- Hiccups

- Intestinal blockage
- Enlarged colon
- Bleeding from the bowels
- Inflammation of the large intestine
- Abnormal lab test results
- Hole in the intestine
- Fatty liver disease
- Skin reactions
- Reactions at the site where the medicine was administered
- Low level of potassium in the blood
- Low level of salt in the blood mostly related with diarrhoea and vomiting
- Muscle cramps
- Kidney problems*
- Low blood pressure*
- Fungal infections
- Viral infections

* Infrequent cases of these events have been observed in patients who experienced episodes of dehydration associated with diarrhoea and/or vomiting, or infections of the blood.

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.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

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
- One 50 ml vial contains 1000 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
50 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,

3526 KV Utrecht,
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	**Name of the medicinal product**
Austria	Irinotecan Accord 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Irinotecan Accord 20 mg/ml concentraat voor oplossing voor infusie
Bulgaria	Irinotecan Accord 20 mg/ml Concentrate for Solution for Infusion
Cyprus	Irinotecan Accord 20 mg/ml Concentrate for Solution for Infusion
Czech Republic	Irinotecan Accordpharma 20 mg/ml koncentrát pro infuzní roztok
Germany	Irinotecan Accord 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Irinotecan Accord
Estonia	Irinotecan Accord
Greece	Irinotecan Accord 20 mg/ml Concentrate for Solution for Infusion
Finland	Irinotecan Accord 20 mg/ml Infuusiokonsentraatti, liuosta varten
Croatia	Irinotekan Accord 20 mg/ml koncentrat za otopinu za infuziju
Hungary	Irinotecan Accord 20 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
Iceland	Irinotecan Accord 20 mg/ml, innrennslisþykkni, lausn
Italy	Irinotecan Accord
Latvia	Irinotecan Accord 20 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Irinotecan Accord 20 mg/ml koncentratas infuziniam tirpalui
Malta	Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
Poland	Irinotecan Accord
The Netherlands	Irinotecan Accord 20 mg/ml concentraat voor oplossing voor infusie
Norway	Irinotecan Accord
Portugal	Irinotecano Accord
Romania	Irinotecan Accord 20 mg/ml concentrat pentru solutie perfuzabila
Slovak Republic	Irinotecan Accord 20 mg/ml infúzny koncentrát
Slovenia	Irinotekan Accord 20 mg/ml koncentrat za raztopino za infundiranje
Sweden	Irinotecan Accord 20 mg/ml, koncentrat till infusionsvätska, lösning
United Kingdom	Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion
Spain	Irinotecan Accord 20 mg/ml concentrado para solución para perfusión EFG
France	IRINOTECAN ACCORD 20 mg/ml, Solution à diluer pour perfusion

The leaflet was last revised in 07/2022.

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.