

IRINOCORD 20 mg/mL

Irinotecan hydrochloride trihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IRINOCORD.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with IRINOCORD against the expected benefits it will have for you.

Ask your doctor if you have any concerns about being treated with this medicine.
Keep this leaflet.

You may need to read it again.

What IRINOCORD are used for

IRINOCORD is used to treat bowel cancer, which has spread to other parts of the body. Cancer, which has spread, cannot be treated by surgery alone and one of the options in this situation is treatment with an anticancer medicine, known as chemotherapy.

IRINOCORD may be used once spread of cancer beyond the bowel is first diagnosed. At this time IRINOCORD will be given in combination with other anticancer medicines. Alternatively, IRINOCORD is used alone when the cancer has not responded or has returned after initial treatment.

Ask your doctor if you have any questions about why

IRINOCORD has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Use in children

It is not known if IRINOCORD is safe and effective in the treatment of children.

Before you are given IRINOCORD

When IRINOCORD must not be given

IRINOCORD must not be given if you:

- are allergic to irinotecan hydrochloride or any of the ingredients listed at the end of this leaflet
- are or may become pregnant
- are breastfeeding or intend to breastfeed

Before treatment with IRINOCORD

You should only be treated with Irinotecan Hydrochloride Trihydrate Injection by a doctor who is experienced in treating patients with cancer. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel.

It is likely that your doctor will give you one or more medicines before administering IRINOCORD to help stop you vomiting or feeling sick after the

treatment. You will probably also have blood tests before each treatment.

You should tell your doctor if:

- you are 65 years of age or older
- you have or have had liver disease, kidney disease or heart disease
- you have previously been treated with radiation therapy
- you have diabetes or asthma
- you have constipation or difficulty urinating
- you have hereditary fructose intolerance
- you are going to be vaccinated (have an injection to prevent a certain disease)

If you have not told your doctor about any of the above, tell your doctor before you are given IRINOCORD.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and IRINOCORD may interfere with each other. In particular, tell your doctor if you are taking:

- laxatives (e.g. for constipation)
- diuretics (medicines which make you pass urine more frequently e.g. for heart disease)
- any medicine for nausea or diarrhoea

- dexamethasone (may be used to treat skin diseases, asthma or other allergic disorders)
- anticonvulsants used to treat seizures
- St Johns Wort, a herbal medicine used to treat depression
- ketoconazole used to treat fungal infections.

Ask your doctor or other health care professional if you are not sure about this list of medicines.

You may need to take different amounts of your medicines or you may need to use different medicines. Your doctor will advise you.

How IRINOCORD is given

IRINOCORD will be given to you by your doctor. It is diluted and given by slow infusion into a vein over a period of 90 minutes.

It is recommended that IRINOCORD be given in different treatment courses depending on whether Irinotecan Hydrochloride Trihydrate Injection is given alone or in combination with other anticancer medicines.

When IRINOCORD is given in combination, treatment courses are of 6 weeks duration given either weekly or fortnightly. Rest periods of 1 or 2 weeks are incorporated into the 6 week courses.

When IRINOCORD is given alone, treatment courses IRINOCORD being given weekly for 4 weeks followed by a 2 week rest period and Irinotecan Hydrochloride Trihydrate Injection being given once every 3 weeks.

Depending on your response, treatment courses may be repeated more than once.

It is recommended that treatment with IRINOCORD should be interrupted if you get severe diarrhoea or other intolerable side effects.

Dose

The recommended dose for IRINOCORD varies between 125 mg/m² and 350mg/m² (based on body surface area), depending on the dosing schedule.

Your doctor will decide the dose of IRINOCORD to be given.

Ask your doctor if you want more information about the dose of IRINOCORD and the other medicines you will be receiving and how they are given.

After your first treatment course, the dose of IRINOCORD may be increased by your doctor if you have not had too many side effects.

Your doctor will lower the dose or stop treatment if you have serious side effects, particularly diarrhoea or changes appearing in your blood tests.

In case of overdose

Overdose is unlikely as treatment will be given in hospital under the supervision of a doctor. The possible effects of overdose are the same as those listed below under side effects.

Tell your doctor immediately if you do not feel well while being given IRINOCORD

While you are using IRINOCORD

Things you must do

Keep all appointments with your doctor and always discuss with your doctor any

problems during or after treatment with IRINOCORD.

Tell your doctor as soon as possible if diarrhoea occurs.

Diarrhoea is a common side effect of IRINOCORD. If untreated, severe diarrhoea can be life-threatening.

Your doctor will prescribe loperamide (an antidiarrhoeal) for you to take in case you get diarrhoea after treatment. You should start taking loperamide, when you first have poorly formed or loose stools or bowel movements more frequent than you would normally expect.

You must tell your doctor if you cannot get diarrhoea under control within 24 hours after taking loperamide.

You should not take loperamide for more than 48 hours.

Also tell your doctor if you develop a fever in addition to the diarrhoea.

In these cases, your doctor may give you antibiotics. If the diarrhoea or fever persists you may become dehydrated and need to go to hospital for treatment.

You may need to take antibiotics if there are changes in your blood tests indicating a lack of white blood cells. Symptoms of this may include frequent infections such as fever, severe chills, sore throat or mouth ulcers. If this persists, you may need to go to hospital for treatment. If you have severe stomach cramps you may need to be treated with antibiotics.

You must use a reliable method of contraception

(birth control) while being treated with IRINOCORD.

If pregnancy occurs, consult your doctor.

Things you must not do

Because of the risk of diarrhoea, do not take laxatives during treatment courses with IRINOCORD.

Talk to your doctor if you need more information about this.

Do not start taking any other medicines, prescription or not, without first telling your doctor or pharmacist.

Side effects

IRINOCORD, like all other medicines, may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as IRINOCORD and they may be severe. Deaths have occurred which, in some cases, may have been related to treatment.

Tell your doctor immediately if you get any of the following side effects:

- diarrhoea
- start to vomit
- develop a fever or any type of infection
- fainting, light-headedness or dizziness
- bloody or black stools
- cannot eat or drink due to nausea or vomiting.

The above side effects may be serious. You may need urgent medical attention.

Very common side effects (occurring in over 50% of patients) are:

- diarrhoea or stomach cramps; may occur early (during or shortly after a treatment) or late (usually more than 24 hours after treatment)
- nausea, vomiting, loss of appetite

- anaemia which may make you weak and light-headed or may cause you to faint
- increased risk of infections including severe infections
- weakness
- hair loss.

Common side effects (occurring in 10-50% of patients) are:

- constipation, flatulence (passing wind), sore mouth, heartburn
- fever (increased body temperature), chills, headache, back pain or other types of pain, infection, fluid retention which results in swelling
- weight loss, dehydration
- runny nose or eyes, increased saliva, sweating or flushing
- skin rash
- coughing, difficulty breathing
- difficulty sleeping or dizziness.

Less common side effects (occurring in less than 10% of patients) are:

- increased risk of bleeding
- severe fever associated with a reduction in white blood cell numbers
- bleeding from the bowel
- jaundice (yellowing of skin and eyes)
- severe breathing difficulties
- generally feeling unwell
- abnormal manner of walking
- fungal infections (e.g. thrush)
- kidney problems.
- Problems speaking

In addition to the above side effects the following have also been reported:

- allergic reactions; some of the symptoms of an allergic reaction may include: rash, itching or hives on the skin. In more severe cases symptoms may also include shortness of breath, wheezing or difficulty breathing, swelling of the face,

- lips, tongue or other parts of the body
- pins and needles
- abdominal bloating and/or pain
- chest pains
- hiccups.

Other side effects not listed above may happen in some people. Some of these side effects can only be found when your doctor does tests to check your progress.

Rare side effects of Irinotecan Hydrochloride Trihydrate Injection have also been reported. These include effects on the heart and blood vessels such as:

- slowed heart beat
- fainting
- blackouts
- blood clots
- swelling and redness along a vein, which is extremely tender when touched
- chest pains
- heart attack
- stroke.

Your doctor has information on monitoring for such side effects and their treatment. A very small number of patients have died suddenly while on Irinotecan Hydrochloride Trihydrate.

Tell your doctor as soon as possible if you experience any side effects, including any effects not listed above.

After taking IRINOCORD

IRINOCORD will normally be stored in a hospital. It should be stored below 25°C. and should be protected from light (kept in the packaging before use).

IRINOCORD must never be frozen.

The product should be diluted and used immediately after opening.

Irinotecan Hydrochloride Trihydrate Injection must be diluted prior to infusion in 5% Dextrose Injection or 0.9% Sodium Chloride Injection to a final concentration range of 0.12 to 2.8 mg/mL.

Irinotecan Hydrochloride Trihydrate Injection has been shown to be chemically and physically stable when diluted with infusion solutions (0.9% sodium chloride solution and 5% glucose solution) for up to 28 days when stored in low-density polyethylene (LDPE) or polyvinyl chloride (PVC) containers at 5°C or at 30°C/ambient humidity and protected from light. When exposed to light, chemical and physical stability is indicated for up to 3 days.

From a microbiological point of view, the product 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 room temperature up to 15-25 °C and for 48 hours at 2-8°C, unless reconstitution / dilution (etc) has taken place in controlled and validated aseptic conditions.

All items used for preparation, administration or otherwise coming into contact with Irinotecan should undergo disposal according to local guidelines for the handling of cytotoxic compounds.

use only and is contained in an outer carton.

Ingredients

The active ingredient in IRINOCORD is irinotecan hydrochloride. There is 20 mg of irinotecan hydrochloride in each 1 ml of IRINOCORD

IRINOCORD also contains:

- sorbitol,
- lactic acid
- water for injections.
- sodium hydroxide
- hydrochloric acid.

Distributed in New Zealand by:

Arrow Pharmaceuticals
(NZ) Ltd.
PO Box 128244.
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Date of Preparation:

4th October 2010

Product description

What it looks like

IRINOCORD is a sterile, clear, pale yellow, solution in a vial. It is available in 2 sizes: 40 mg/2 mL and 100 mg/5 mL. Each vial is for single