Irinotecan ACT Injections

contains the active ingredient irinotecan hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Irinotecan ACT.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Irinotecan ACT against the benefits they expect it will have for you.

If you have any concerns about being treated with this medicine, talk to your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Irinotecan ACT is used for

Irinotecan ACT 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.

Irinotecan ACT may be used once spread of cancer beyond the bowel is first diagnosed. At this time Irinotecan ACT will be given in combination with other anticancer medicines. Alternatively, Irinotecan ACT 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 Irinotecan ACT has been prescribed for you.
Your doctor may have prescribed it for another purpose.

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

Before being treated with Irinotecan ACT

When Irinotecan ACT must not be given

Irinotecan ACT must not be given if you are allergic to medicines containing irinotecan hydrochloride or any of the ingredients listed at the end of this leaflet.

Irinotecan ACT must not be given if you are, or may be, pregnant.

Irinotecan ACT must not be given if you are breastfeeding or intend to breastfeed.

Before treatment with Irinotecan ACT

You should be treated with Irinotecan ACT 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 Irinotecan ACT to help stop you vomiting or feeling sick after the treatment. You will probably also have a blood test before each treatment.

Tell your doctor if you are 65 years of age or older.

Tell your doctor if you have or have had liver disease, kidney disease or heart disease.

Tell your doctor if you have previously been treated with radiation therapy.

Tell your doctor if you have diabetes or asthma.

Tell your doctor if you have constipation or difficulty urinating.

Tell your doctor if you have hereditary fructose intolerance.

Tell your doctor if you have Crigler-Najjar syndrome or Gilbert's syndrome.

Tell your doctor if 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 them before you are given Irinotecan ACT.

Taking other medicines

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

Some medicines may be affected by Irinotecan ACT, or may affect how well it works. These include:

- 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 John's Wort, a herbal medicine used to treat depression
- ketoconazole, used to treat fungal infections.

Your doctor will advise you what to do if you are taking any of these medicines. You may need to take different amounts of your medicines or you may need to use different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor, pharmacist or nurse.

How Irinotecan ACT is given

Irinotecan ACT 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 Irinotecan ACT be given in different treatment courses depending on whether Irinotecan ACT is given alone or in combination with other anticancer medicines.

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

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

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

Dosage used for treatment with Irinotecan ACT

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

Your doctor will decide the dose of Irinotecan ACT to be given.

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

After your first treatment course, the dose of Irinotecan ACT 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 with Irinotecan ACT

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 Irinotecan ACT.

While being treated with Irinotecan ACT

Things you must do

Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with Irinotecan ACT.

Tell your doctor as soon as possible if diarrhoea occurs.

Diarrhoea is a common side effect of Irinotecan ACT. If untreated, severe diarrhoea can be life-threatening. Your doctor will prescribe loperamide (a medicine to treat diarrhoea) 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 Irinotecan ACT. 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 Irinotecan ACT.
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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Irinotecan ACT.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following:

- 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
- bloating or pain in upper stomach
- 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 ACT 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 ACT.

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

After treatment with Irinotecan ACT

Storage

Irinotecan ACT will normally be stored in a hospital. It should be stored below 30°C and should be protected from light (kept in the packaging before use). Irinotecan ACT must never be frozen.

Product description

What it looks like

Irinotecan ACT Injections come in 3 sizes:

- 40 mg irinotecan hydrochloride /2 mL
- 100 mg irinotecan hydrochloride /5 mL
- 500 mg irinotecan hydrochloride /25 mL.

Irinotecan ACT is a sterile, pale yellow, clear solution for injection.

Each Irinotecan ACT vial is for single use only.

Ingredients

The active ingredient in Irinotecan ACT is irinotecan hydrochloride. Each mL of Irinotecan ACT contains 20 mg of irinotecan hydrochloride.

The vials also contain:

- sorbitol
- (s) - lactic acid
- water for injections.

The solution may also contain sodium hydroxide or hydrochloric acid.

Supplier

Amneal Pharma Australia Pty Ltd
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Australian Registration Numbers:

Irinotecan ACT (40 mg/2 mL) - AUST R 227305

Irinotecan ACT (100 mg/5 mL) - AUST R 227306

Irinotecan ACT (500 mg/25 mL) - AUST R 227307

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