

IRINOTECAN EBEWE

irinotecan hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Irinotecan Ebewe.

It does not contain all 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 against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet

You may need to read it again.

It is important to remember that Irinotecan Ebewe is a **PRESCRIPTION ONLY MEDICINE**.

Irinotecan Ebewe will only be given to you by specially trained personnel in a hospital environment.

What Irinotecan Ebewe is used for

Irinotecan Ebewe belongs to the group of medicines called antineoplastics or cytotoxic medicines.

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

Your doctor may have prescribed it for another purpose.

Before you are given Irinotecan Ebewe

When you must not be given this medicine:

You must not be given this medicine if you have had an allergic reaction to Irinotecan Ebewe or to any of the ingredients listed at the end of this leaflet (see Product Description).

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body

- rash, itching, hives or flushed, red skin
- dizziness or light-headedness
- back pain

You must not be given this medicine if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, Irinotecan Ebewe is not recommended to be given during pregnancy. If there is a need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks involved.

You must not be given this medicine if you are breast-feeding or plan to breast feed.

It is recommended that you do not breast-feed while you are receiving Irinotecan Ebewe, as it is not known whether Irinotecan passes into breast milk.

You must not be given this medicine if the packaging is torn or shows signs of tampering.

You must not be given this medicine after the expiry date printed on the pack.

Use in children

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

Before you are given this medicine

You should only be treated with Irinotecan Ebewe 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.

You will probably feel nauseous and have diarrhoea, vomiting, stomach cramping and possibly infections during or after treatment with Irinotecan Ebewe.

It is likely that your doctor will give you one or more medicines before administering Irinotecan Ebewe, which will help stop you vomiting or feeling sick after the treatment. You will probably also have a blood test 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 Irinotecan Ebewe.

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

Some medicines and Irinotecan Ebewe 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 Irinotecan Ebewe is given

How it is given

This medicine is given as an infusion (drip) into your veins over a 90 minute period.

Your doctor or nurse will inject the medicine for you. **Never inject this medicine yourself.**

Always let your doctor or nurse do this.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

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

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

After your first treatment course, the dose of Irinotecan Ebewe 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.

How often it will be given

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

When Irinotecan Ebewe 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 Ebewe is given alone, treatment courses

include Irinotecan Ebewe being given weekly for 4 weeks followed by a 2 week rest period and Irinotecan Ebewe 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 Ebewe should be interrupted if you get severe diarrhoea or other intolerable side effects.

In Case of Overdose

As Irinotecan Ebewe is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given Irinotecan Ebewe, tell your doctor immediately.

While you are being given Irinotecan Ebewe

Things you MUST do:

- **Be sure to keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some blood tests and other tests from time to time to check on your progress and detect any unwanted side effects.
- **Tell all doctors and health care professionals who are treating you that you are being given Irinotecan Ebewe.**

- **Tell your doctor as soon as possible if diarrhoea occurs.** Diarrhoea is a common side effect of Irinotecan Ebewe. 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.

- **If you are about to be started on any new medicine, tell your doctor or health care professional that you are being given Irinotecan Ebewe.**
- **You must use a reliable method of contraception (birth control) while being treated with Irinotecan Ebewe. If pregnancy occurs, consult your doctor.**

Things to be careful of:

- **Do not drive or operate machinery after receiving this medicine until you know how it affects you.** Irinotecan Ebewe may cause sleepiness in some people.

Things you MUST NOT do:

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

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 health care professional as soon as possible if you do not feel well while you are being given Irinotecan Ebewe.

Like other medicines that treat cancer, Irinotecan Ebewe may have unwanted side effects, some of which may be serious. Deaths have occurred which, in some cases, may have been related to treatment. You may need medical treatment if you experience some of the side effects.

Ask your doctor or health care professional to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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.

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 Ebewe 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 Ebewe.

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

Storage

Irinotecan Ebewe will be stored appropriately at the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product Description

What it looks like

Irinotecan Ebewe is a clear, light yellow solution, supplied in an amber glass vial.

Ingredients

Active Ingredients:

Irinotecan Ebewe contains the active ingredient Irinotecan hydrochloride (as trihydrate) 20mg/mL

Other ingredients:

Irinotecan Ebewe also contains sorbitol, lactic acid, sodium hydroxide and water for injections.

glass vial (packs of 1 vial and 5 vials).

AUST R 154239 Irinotecan Ebewe 150mg/7.5mL in 10mL glass vial (packs of 1 vial and 5 vials).

AUST R 154240 Irinotecan Ebewe 300mg/15mL in 20mL glass vial (single vial).

AUST R 154238 Irinotecan Ebewe 500mg/25mL in 50mL glass vial (single vial).

This leaflet was prepared in September 2009

Manufacturer

Irinotecan Ebewe is made by:
EBEWE Pharma Ges.m.b.H.
Nfg. KG
A-4866 Unterach
Austria

Sponsor

Irinotecan Ebewe is distributed in Australia by:
InterPharma Pty Ltd
Suite 3, 14 Sydney Road
Manly
NSW 2095

Distributed in New Zealand by:
Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland, New Zealand
(on behalf of InterPharma Pty Ltd)

Irinotecan Ebewe can be identified by an Australian Register Number, which is found on the packaging:

AUST R 154241 Irinotecan Ebewe 40mg/2mL in 2mL glass vial (packs of 1 vial and 5 vials).

AUST R 154237 Irinotecan Ebewe 100mg/5mL in 5mL