
IRINOTECAN ACTAVIS 40 (Irinotecan 40 mg/2mL Concentrated Injection) And IRINOTECAN ACTAVIS 100 (Irinotecan 100 mg/5mL Concentrated Injection)

Consumer Medicine Information

May 2009

What is in this leaflet

Please read this leaflet carefully before being treated with IRINOTECAN ACTAVIS 40 & 100.

This leaflet answers some common questions about IRINOTECAN ACTAVIS. It does not contain all the available information and 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 IRINOTECAN ACTAVIS 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 even after your treatment with IRINOTECAN ACTAVIS is finished. You may need to read it again.

What IRINOTECAN ACTAVIS is used for

IRINOTECAN ACTAVIS contains the active ingredient, irinotecan hydrochloride.

IRINOTECAN ACTAVIS belongs to a class of medicines called antineoplastic or cytotoxic medicines. This medicine works by stopping cancer cells from growing and multiplying

IRINOTECAN ACTAVIS 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 ACTAVIS may be used once spread of cancer beyond the bowel is first diagnosed. At this time IRINOTECAN ACTAVIS will be given in combination with other anticancer medicines.

Alternatively, IRINOTECAN ACTAVIS may be used alone when the cancer has not responded or has returned after initial treatment. Your doctor may prescribe IRINOTECAN ACTAVIS for another purpose. Ask your doctor if you have any questions about why IRINOTECAN ACTAVIS has been prescribed for you.

Some information about IRINOTECAN ACTAVIS is provided below. **However, always talk to your doctor if you have concerns or questions about your treatment.**

Use in Children

There is not enough information available to recommend the use of this medicine in children.

Before you are given IRINOTECAN ACTAVIS

When IRINOTECAN ACTAVIS must not be given

IRINOTECAN ACTAVIS must not be given if you:

- are allergic to irinotecan hydrochloride,
- are allergic to any of the other ingredients listed at the end of this leaflet.
- You are, or are thinking about becoming pregnant
- You are breastfeeding or intend to breast-feed.

Symptoms of an allergic reaction to IRINOTECAN ACTAVIS may include shortness of breath, wheezing or difficulty breathing or a tight feeling in your chest; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; dizziness or light-headedness.

Before being treated with IRINOTECAN ACTAVIS:

You should only be treated with IRINOTECAN ACTAVIS by a doctor who is experienced in treating patients with cancer (oncologist). 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 ACTAVIS.

It is likely that your doctor will give you one or more medicines before administering IRINOTECAN ACTAVIS, 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 ACTAVIS

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 IRINOTECAN ACTAVIS 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 e.g. skin diseases, asthma or other allergic disorders)
- anti-convulsants used to treat seizures

- St Johns Wort a herbal medicines used to treat depression

- ketoconazole, an oral antifungal medicine.

- Atazanavir sulfate (a treatment for HIV infection)

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.

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Like most cytotoxic medicines IRINOTECAN ACTAVIS is not recommended for use during pregnancy. If there is any need to consider IRINOTECAN ACTAVIS during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are being given IRINOTECAN ACTAVIS or shortly after you have stopped treatment with IRINOTECAN ACTAVIS.

IRINOTECAN ACTAVIS might cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of contraceptive whilst you are being given IRINOTECAN ACTAVIS and for at least 12

weeks after you stop treatment. A barrier method of birth control, such as a condom, should be used while you are being given IRINOTECAN ACTAVIS and for the first week of this 12 week period. Your doctor will discuss this with you.

Do not breast-feed if you are being treated with this medicine. IRINOTECAN ACTAVIS might pass into breast milk and there is a possibility that your baby may be affected.

If you are not sure whether you should start using IRINOTECAN ACTAVIS, talk to your doctor.

How IRINOTECAN ACTAVIS is given

Your doctor will decide what dose you will receive. This depends on your condition and several other factors including your height, weight, white blood cell count, liver function, and whether or not other chemotherapy medicines are also being given.

IRINOTECAN ACTAVIS 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 ACTAVIS be given in different treatment courses depending on whether IRINOTECAN ACTAVIS is given alone or in combination with other anticancer medicines. When IRINOTECAN ACTAVIS 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 ACTAVIS is given alone,

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

Dose

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

Your doctor will decide the dose of IRINOTECAN ACTAVIS to be given.

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

After your first treatment course, the dose of IRINOTECAN ACTAVIS 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.

Overdose

Overdose is unlikely as treatment will be given 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.

While you are being given IRINOTECAN ACTAVIS

Things you must do

Keep all appointments with your doctor and always discuss with your doctor any problems during or after treatment with IRINOTECAN ACTAVIS. Diarrhoea is a common side effect of IRINOTECAN ACTAVIS.

Tell your doctor as soon as possible if diarrhoea occurs. 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. Also tell your doctor if you develop a fever in addition to the diarrhoea.

You should not take loperamide for more than 48 hours. 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, 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 ACTAVIS. However, if pregnancy occurs during treatment, consult your doctor.

Things you must not do

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

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 given IRINOTECAN ACTAVIS.

IRINOTECAN, like all other medicines, may cause unwanted side effects. Side effects are very common with anti-cancer medicines such as IRINOTECAN ACTAVIS 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 the following side effects

- diarrhoea
- start to vomit
- develop a fever or any type of infection

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- fainting, light-headedness or dizziness
- have bloody or black stools
- cannot eat or drink due to nausea or vomiting.
- increased risk of bleeding
- severe fever associated with a reduction in white blood cell numbers
- ulceration and 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.

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

Side effects of IRINOTECAN ACTAVIS are:

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

- 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):

- 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):

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

- cases of inflammation of the large bowel (colon),
- 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 ACTAVIS 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 ACTAVIS. Tell your doctor as soon as possible if you experience any side effects, including any effects not listed above.

After using IRINOTECAN ACTAVIS

Storage

IRINOTECAN ACTAVIS 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 ACTAVIS must never be frozen.

Product description

What IRINOTECAN ACTAVIS looks like

IRINOTECAN is a sterile, pale yellow, clear fluid for injection supplied as 2 or 5 millilitres (mL) in amber glass vials. Each vial is for single use contained within an outer carton.

Ingredients

The active ingredient in IRINOTECAN ACTAVIS is irinotecan hydrochloride. There are 20 milligrams of irinotecan hydrochloride in 1 mL of IRINOTECAN ACTAVIS. Other ingredients are sorbitol, lactic acid, sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

Actavis Australia Pty Ltd
Upper Ground Floor

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Irinotecan Actavis 40 & Irinotecan Actavis 100 (40mg/2mL and 100mg/5 mL)

183 Melbourne Street
North Adelaide
South Australia 5006
ABN 43 122 896 468
Phone Number:1300 881 893

Solely distributed in Australia by:
Generic Health Pty Ltd.,
Suite 1, 1175 Toorak Road,
Camberwell VIC 3124.

- 40 mg/2mL Single-Use Vial,
Carton of 1 vial (AUST R
144972).

- 100 mg/5mL Single-Use Vial,
Carton of 1 vial (AUST R
144985).

This leaflet was prepared in
May 2009

Distributor in Australia: