

IRINOTECAN ACCORD

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Irinotecan Accord?

Irinotecan Accord contains the active ingredient irinotecan hydrochloride trihydrate. Irinotecan Accord is used to treat bowel cancer, which has spread to other parts of the body. Irinotecan Accord may be used once spread of cancer beyond the bowel is first diagnosed. At this time Irinotecan Accord will be given in combination with other anticancer medicines. Alternatively, Irinotecan Accord is used alone when the cancer has not responded or has returned after initial treatment.

For more information, see Section [1. Why am I using Irinotecan Accord?](#) in the full CMI.

2. What should I know before I use Irinotecan Accord?

Do not use if you have ever had an allergic reaction to irinotecan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Irinotecan Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Irinotecan Accord and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Irinotecan Accord?

Irinotecan Accord is an injection and will be given to you by your doctor or nurse.

More instructions can be found in Section [4. How do I use Irinotecan Accord?](#) in the full CMI.

5. What should I know while using Irinotecan Accord?

Things you should do	<ul style="list-style-type: none">• Tell your doctor as soon as possible if diarrhoea occurs. Diarrhoea is a common side effect of Irinotecan Accord. If untreated, severe diarrhoea can be life-threatening• Remind any doctor, dentist or pharmacist you visit that you are using Irinotecan Accord.• Be sure to keep all your doctor's appointments so your progress can be checked.• Keep follow up appointments with your doctor. It is important to have your follow-up doses of Irinotecan Accord at the appropriate times to get the best effects from your treatments.
Driving or using machines	<ul style="list-style-type: none">• Irinotecan Accord may cause dizziness or visual disturbances which may occur within 24 hours following the administration of irinotecan in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.• Be careful when drinking alcohol while you are being given this medicine. If you drink alcohol, dizziness light-headedness and diarrhoea may be worse.

For more information, see Section [5. What should I know while using Irinotecan Accord?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the more common side effects are included in full below in the CMI. Speak to your doctor if you have any of these common side effects and they worry you.

The very serious side effect are:

- inability to control diarrhoea within 24 hours after taking loperamide
- any signs of infection such as fever, chills, sore throat or cough, low back or side pain, painful or difficult urination
- symptoms of dehydration, such as faintness, light-headedness or dizziness, increased thirst, wrinkling of the skin
- inability to drink due to nausea or vomiting
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, hives on the skin
- unusual bleeding or bruising (such as bloody or black stools, blood in urine)
- yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice)
- chest pain
- heart and blood vessels related side effects such as slowed heartbeat, fainting, blackout, blood clot, heart attack or stroke

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

IRINOTECAN ACCORD

Active ingredient: *irinotecan hydrochloride trihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Irinotecan Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Irinotecan Accord.**

Where to find information in this leaflet:

- [1. Why am I using Irinotecan Accord?](#)
- [2. What should I know before I use Irinotecan Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Irinotecan Accord?](#)
- [5. What should I know while using Irinotecan Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Irinotecan Accord?

Irinotecan Accord contains the active ingredient irinotecan hydrochloride trihydrate. Irinotecan belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. These medicines are used to kill cancer cells.

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

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

2. What should I know before I use Irinotecan Accord?

Warnings

Do not use Irinotecan Accord if:

- you are allergic to irinotecan or any of the ingredients listed at the end of this leaflet

Check with your doctor if you have or have had:

- liver problems, including liver disease or raised enzymes
- kidney disease or have difficulty urinating
- problems with your heart or blood vessels
- been treated with radiation therapy
- diabetes

- asthma
- constipation or obstruction of the bowel
- diarrhoea or have taken anti-diarrhoea medication within the last 24 hours
- hereditary fructose intolerance
- Crigler-Najjar syndrome or Gilbert's syndrome
- are going to be vaccinated (have an injection to prevent a certain disease)
- an infection or high temperature
- allergies to any other medicines, foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Pregnancy should be avoided if you or your partner is receiving Irinotecan Accord.

As with many medicines, Irinotecan Accord may harm your developing or breastfeeding baby.

Females: Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Avoid becoming pregnant by using effective contraception during treatment and up to 6 months after therapy.

Males: Tell your doctor or pharmacist if your partner intends to become pregnant while you are being given Irinotecan Accord, or shortly after you have stopped treatment with irinotecan.

It is recommended that you use effective contraception while you are using Irinotecan Accord and for at least 3 months after you stop treatment.

Do not breast-feed if you are taking this medicine.

Irinotecan passes into breast milk and there is a possibility that your baby may be affected.

3. What if I am taking other medicines?

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

Some medicines may interfere with Irinotecan Accord and affect how it works or Irinotecan Accord may affect how they work.

- laxatives (for constipation)
- diuretics (medicines which make you pass urine more frequently e.g. for heart disease)
- any medicine used to treat nausea or vomiting
- dexamethasone (also called a glucocorticoid), which may be used to prevent nausea or vomiting, or 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.
- atazanavir, used to treat HIV-1 infection
- prochlorperazine, used to treat nausea, vomiting and dizziness
- suxamethonium or other medicines used as an anaesthetic
- other medicines used to treat cancer

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Irinotecan Accord.

4. How do I use Irinotecan Accord?

How much to use

Irinotecan Accord is given to you as a slow injection into your vein (intravenously) by your doctor or nurse.

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

Irinotecan may be given alone or in combination with other medicines to treat cancer.

Several treatment courses of irinotecan may be needed, depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of irinotecan you will be receiving

When to use Irinotecan Accord

It is very important that you continue to receive Irinotecan Accord for as long as your doctor prescribes it. Your doctor will decide how many cycles of treatment you need.

If you use too much Irinotecan Accord

It is unlikely that you will receive an overdose of Irinotecan Accord because a trained nurse or doctor will give it. If you think that you have been given too much Irinotecan Accord, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Irinotecan Accord?

Things you should do

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

with Irinotecan Accord.

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Irinotecan Accord.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that:

- your progress can be checked
- you have your follow up doses of Irinotecan Accord.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to make sure the medicine is working and to prevent unwanted side effects. It is also important to have your follow-up doses of Irinotecan Accord at the appropriate times to get the best effects from your treatments.

Things you should not do

Do not take any laxatives without checking with your doctor.

Diarrhoea is a common side effect of irinotecan. Taking laxatives, even if you are constipated, may cause or worsen diarrhoea.

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

Precautions to take

This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. Avoid people who have infections to reduce your risk of infection

or bleeding.

Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.

Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.

Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.

Avoid contact sports or other situations where you may bruise or get injured.

Take precautions to protect other people while you are receiving chemotherapy and for one week after the treatment period. Your body breaks down irinotecan and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

Take the following precautions:

- flushing the toilet twice to dispose of any body fluids and waste
- wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet
- washing linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water
- placing soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage
- use a barrier method such as a condom, for sexual intercourse

Make sure you know what to do if you experience nausea, vomiting or diarrhoea.

You may feel nauseous, and have vomiting, diarrhoea, and/or stomach cramping, during or after treatment with irinotecan. This can lead to dehydration. It is likely that your doctor will give you one or more medicines to help manage these side effects.

Driving or using machines

Be careful driving or operating machinery until you know how Irinotecan Accord affects you.

This medicine may cause dizziness or visual disturbances which may occur within 24 hours following the administration of irinotecan in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are being given this medicine. If you drink alcohol, dizziness, light-headedness and diarrhoea may be worse.

Looking after your medicine

The hospital will store Irinotecan Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Irinotecan Accord that may be left over.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">• nausea• loss of appetite• weight loss• hair loss• constipation (remember do not take laxatives)• heartburn, indigestion, hiccups• bloating, excessive wind• sore mouth, mouth ulcers• difficulty sleeping• headache	Speak to your doctor if you have any of these common side effects and they worry you. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• vomiting• abdominal cramping/pain• runny nose or eyes, increased salivation, sweating or flushing• shortness of breath when exercising, dizziness, looking pale and walking abnormally• unusual tiredness or weakness• swelling and redness along a vein• fluid retention that results in swelling.• fungal infections (e.g. thrush)	Call your doctor or nurse as soon as possible.

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• inability to control diarrhoea within 24 hours after taking loperamide• any signs of infection such as fever, chills, sore throat or cough, low back or side pain, painful or difficult urination• symptoms of dehydration, such as faintness, light-headedness or dizziness, increased thirst, wrinkling of the skin	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital.

- inability to drink due to nausea or vomiting
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, hives on the skin
- unusual bleeding or bruising (such as bloody or black stools, blood in urine)
- yellowing of the skin and/or eyes (these may be symptoms of a type of liver disease called jaundice)
- chest pain
- heart and blood vessels related side effects such as slowed heartbeat, fainting, blackout, blood clot, heart attack or stroke

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Irinotecan Accord contains

Active ingredient (main ingredient)	Irinotecan hydrochloride trihydrate
Other ingredients (inactive ingredients)	Sorbitol Lactic acid Sodium hydroxide Hydrochloric acid Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Irinotecan Accord looks like

Irinotecan Accord is a sterile, pale yellow, clear, aqueous solution. (40 mg/2 mL Aust R 209856, 100 mg/5 mL Aust R 209857, 300 mg/15 mL AUST R 316415, 500 mg/25 mL AUST R 316412)

Who distributes Irinotecan Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street