Applicant : Eurolab (Pty) Ltd
Proprietary name : Irinotas & Irinotas 100
Dosage form and strength : Solution for infusion 40 mg & 100 mg
Date of submission : 22 November 2024
Approval date : 11 February 2025

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

IRINOTAS 40 mg/2 mL Solution for Infusion

IRINOTAS 100 mg/5 mL Solution for Infusion

Irinotecan hydrochloride trihydrate

Contains sorbitol

Read all of this leaflet carefully before you start taking IRINOTAS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **IRINOTAS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **IRINOTAS** is and what it is used for
2. What you need to know before you are given **IRINOTAS**
3. How **IRINOTAS** will be given
4. Possible side effects
5. How to store **IRINOTAS**
6. Contents of the pack and other information

1. What IRINOTAS is and what it is used for

IRINOTAS belongs to a group of medicines called cytostatics (anti-cancer medicines).

IRINOTAS is used for the treatment of advanced cancer of the colon and rectum, either in a combination with other medicines or alone.

Your doctor may use a combination of **IRINOTAS** with 5- fluorouracil/folinic acid (5FU/FA) to treat your cancer of the large intestine (colon or rectum).

2. What you need to know before you are given IRINOTAS

IRINOTAS should not be administered to you

- if you are hypersensitive (allergic) to Irinotecan Hydrochloride or any of the other ingredients of **IRINOTAS** (listed in section 6).
- if you have or have had chronic inflammatory bowel disease or bowel obstruction.
- if you are Pregnant or breast feeding or if you think you might be pregnant.
- if you have severe liver disease.
- if you have severe bone marrow failure.
- if you are in poor general health (evaluated by an international standard, WHO performance status higher than 2).
- if you are taking azole antifungal medication (used to treat fungal infections) or St John's Wort (a herbal supplement).

Warnings and precautions

As **IRINOTAS** is an anti-cancer medicine it will be administered to you in a special unit and under the supervision of a doctor qualified in the use of anti-cancer medicines. Some people will need special care from their doctors when they are on **IRINOTAS**. It is especially important that

your doctor explains the need for sufficiently prolonged anti-diarrhoeal treatment and abundant fluid intake if you require it.

You may develop diarrhoea soon after treatment or your diarrhoea may start more than 24 hours after administration of **IRINOTAS** (delayed diarrhoea), which if not properly treated can be life-threatening. It is often seen about 5 days after administration. Your doctor will prescribe medicine to help prevent or control this side effect. Make sure you get the medicine right away, so that you will have it at home when you need it.

Immediately after the first liquid stool do the following:

1. Take any anti-diarrhoeal treatment that the doctor has given you, exactly as he/she has told you.

   The treatment may not be changed without consulting the doctor. Recommended anti diarrhoeal treatment is loperamide (4 mg for the first intake and then 2 mg every 2 hours, also during the night). This should be continued for at least 12 hours after the last liquid stool. The recommended dosage of loperamide may not be taken for more than 48 hours.
2. Drink large amounts of water and rehydration fluids immediately (i.e., water, soda water, fizzy drink, soup or oral rehydration therapy).
3. Immediately inform your doctor who is supervising the treatment and tell him/her about the diarrhoea. If you are not able to reach the doctor, contact the unit at the hospital supervising the **IRINOTAS** treatment. It is very important that they are aware of the diarrhoea

Your blood cell count should be monitored weekly as infection may occur due to a decrease in white blood cells. Fever together with a decrease in white blood cells should be urgently treated in hospital. The **IRINOTAS** dose should be delayed or reduced accordingly.

Tell your doctor or health care provider before being given **IRINOTAS**:

- if you have impaired liver function you are at greater risk of developing severe decrease in white blood cells or fever.
- If you experience nausea and vomiting. If you experience vomiting together with delayed diarrhoea, you should be hospitalised for treatment.
- you experience early diarrhoea together with a group of symptoms such as sweating, abdominal cramping, watery eyes and salivation. If this occurs, inform your doctor as a specific medication is required in order for these symptoms to disappear.
- you are an elderly patient, the dose may have to be adjusted accordingly.

Contraceptive measures must be taken during and for at least 3 months after stopping therapy.

Avoid vaccination with live vaccines.

Other medicines and IRINOTAS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

IRINOTAS may interact with the following medicine:

- The effects of Medicines used to cause muscle paralysis/anaesthesia during surgery (neuromuscular blocking agents) may be prolonged when administered together with **IRINOTAS**.
- Other medicines used for cancer therapy (antineoplastic agents) may worsen the diarrhoea and blood disorders that may be experienced when administered together with **IRINOTAS**.

- A cortisone medicine known as dexamethasone used to treat inflammation and also cancer, may enhance the chances of experiencing a decrease in a type of white blood cells (a blood disorder known as lymphocytopenia) when administered together with **IRINOTAS**.
- Laxatives can worsen the incidence or severity of diarrhoea.
- Medicines that increase urination (diuretics) as this, together with the vomiting and diarrhoea that may be experienced with **IRINOTAS**, can result in dehydration.
- Medicines used to treat epilepsy (i.e. anticonvulsants e.g. carbemazepine, phenobarbital or phenytoin) decrease the effect of **IRINOTAS**.
- St. John's Wort may reduce the effect of **IRINOTAS**, when administered together with **IRINOTAS**.
- HIV medicine known as atazanavir may increase the effects of **IRINOTAS**.
- Cancer medicine known bevacizumab may increase the effects of **IRINOTAS**.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Contraception in males and females

Male patients treated with IRINOTAS should use highly effective contraception, while being treated with IRINOTAS and for an additional 3 months after receiving the last dose.

Female patients and female sexual partners of male patients treated with IRINOTAS should use highly effective contraception, while being treated with IRINOTAS and an additional 6 months after receiving the last dose.

You should not use **IRINOTAS** if you are pregnant or breastfeeding your baby.

Driving and using machines

There is potential for dizziness or visual disturbances, and it is advised not to drive or operate machinery if these symptoms occur.

IRINOTAS contains sorbitol

It is unsuitable for use in patients with hereditary fructose intolerance.

3. How IRINOTAS will be given

You will not be expected to give yourself **IRINOTAS**. It will be given to you by a person who is qualified to do so.

IRINOTAS will be given as an infusion into your veins over a period of 30 to 90 minutes.

The amount of infusion you are given will depend on your age, size and general medical condition. It will also depend on any other treatment you may have received for your cancer.

Your doctor will calculate your body surface area in square meters (m^2).

- If you have previously been treated with 5-fluorouracil you will normally be treated with **IRINOTAS** alone starting with a dose of 350 mg/m^2 every 3 weeks.
- If you have not had previous chemotherapy you will normally receive 180 mg/m^2 **IRINOTAS** every two weeks. This will be followed by folinic acid and 5-fluorouracil.

If you receive more IRINOTAS than you should

Since a healthcare professional will administer **IRINOTAS**, he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take IRINOTAS

Since a health care provider will administer **IRINOTAS**, it is unlikely that the dose will be missed.

4. Possible side effects

IRINOTAS can have side effects.

Not all side effects reported for **IRINOTAS** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **IRINOTAS**, please consult your health care provider for advice.

The following conditions have been reported with the use of **IRINOTAS**

Decrease in white blood cells

IRINOTAS may cause a decrease in the number of some of your white blood cells, which play an important role in fighting infections. This is called neutropenia.

Nausea and vomiting

If you have any fever, and particularly if you also have diarrhoea and/or nausea and/or vomiting contact your doctor IMMEDIATELY.

Breathing difficulties

If you have breathing difficulties contact your doctor or nurse IMMEDIATELY.

Sepsis

If you experience fever, difficulty breathing, low blood pressure (feeling that you want to faint), fast heart rate and mental confusion contact your doctor or nurse IMMEDIATELY

These are frequent side effects

- abdominal cramps
- hair loss
- heart problems
- infections
- weight loss, dehydration, decreased blood circulation
- blockage or perforation (a 'hole') in the bowel
- bleeding from the bowel
- inflammation in the bowel
- passing black or blood stained stools
- changes in laboratory tests
- jaundice

These are less frequent side effects

- dizziness
- difficulty walking
- confusion

- headache
- pupils of the eye get smaller
- watering eyes
- excessive mouth watering
- irritation and inflammation inside the nose which may result in stuffy nose, runny nose and/or post-nasal drip
- Rectum problems, fungus in the intestine (monilia), swelling or irritation of the large intestine
- low potassium and/or magnesium in blood
- low blood pressure
- flushing of the skin
- fainting
- slow heart rate
- rash or itching, dry skin, skin discoloration

Frequency of these side effects is unknown

- chills
- sweating
- feeling unwell
- visual disturbance
- inflammation of the eye
- feeling weak
- abdominal pain
- feeling weakness or lack of energy
- cramps

- pins-and-needles sensation in the arms, hands, legs or feet
- vasodilation (widening of blood vessels)
- sweating
- kidney problems
- liver problems

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **IRINOTAS**.

5. How to store IRINOTAS

Single-dose vials of **IRINOTAS** solution for infusion should be stored at or below 25 °C and protected from light.

After dilution in either 0,9 % sodium chloride or 5 % dextrose, the diluted solution is stable for 24 hours at a temperature below 25 ºC or 4 days under refrigeration (2-8 ºC). Discard any unused portion thereafter.

Do not freeze. Keep out of reach of children.

6. Contents of the pack and other information

What IRINOTAS contains

The active substance is Irinotecan hydrochloride trihydrate.

The other ingredients are:

- Lactic acid
- Sorbitol
- Sodium hydroxide
- Hydrochloric acid 37 %
- Water for injection

What IRINOTAS looks like and contents of the pack

A pale yellow, clear solution, free from particles.

IRINOTAS 40: Carton containing one single-dose 2 mL USP type 1 amber tubular glass vial, with a grey rubber stopper and an orange flip-off aluminium seal. (International System of Units)

IRINOTAS 100: Carton containing one single-dose 5 mL USP type 1 amber tubular glass vial, with a grey rubber stopper and an orange or red flip-off aluminium seal. (International System of Units)

Holder of certificate of registration

Eurolab (Pty) Ltd.

Woodmead Office Park, 3 Stirrup Lane

Van Reenens Avenue

Woodmead

2144

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