PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

IROCAN 40 mg/2 ml (Solution for Infusion)

IROCAN 100 mg/5 ml (Solution for Infusion)

IROCAN 300 mg/15 ml (Solution for Infusion)

IROCAN 500 mg/ 25 ml (Solution for Infusion)

Contains: Sorbitol

Read all of this leaflet carefully before you start taking IROCAN

- Keep this leaflet. You may need to read it again
- Ask your health care provider or pharmacist if you need more information.

What is in this leaflet

1. What **IROCAN** is and what it is used for

2. What you need to know before you take **IROCAN**

3. How to take **IROCAN**

4. Possible side effects

5 How to store **IROCAN**

6. Contents of the pack and other information

1. WHAT IROCAN IS AND WHAT IT IS USED FOR:

- **IROCAN** is an anticancer medicine containing the active substance irinotecan hydrochloride, trihydrate. Irinotecan hydrochloride trihydrate interferes with the growth and spread of cancer cells in the body.

- **IROCAN** is indicated in combination with other medicines or as a single medicine for the treatment of patients with advanced or metastatic cancer of the colon or rectum.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IROCAN

Do not take IROCAN:

- If you are allergic to irinotecan hydrochloride trihydrate or any of the other ingredients of **IROCAN** (listed in section 6 “What **IROCAN** contains”)
- If you have chronic inflammatory bowel disease and/or bowel obstruction
- If you are breast-feeding or pregnant or you are of childbearing age (able to give birth to children).
- If your bilirubin level is higher than 1,5 times the upper limit of the normal range
- If you have severe bone marrow failure (a condition that results in energy loss, pale skin, small red dots under skin, easy bruising, recurring/unexplained infections, difficulty in stopping to bleed)
- if you are in poor general condition (WHO performance status higher than 2)
- If you are taking or have recently taken St John’s Wort (a herbal extract containing Hypericum)
- If you are to take or have recently taken live attenuated vaccines (vaccines against yellow fever, chicken pox, shingles, measles, mumps, rubella, tuberculosis, rotavirus, influenza) and during the 6 months after stopping chemotherapy
- If you are a child
- If you are using medicines called azole antifungals (a group of medicines that inhibit the growth of a wide range of fungi e.g. fluconazole, itraconazole, terbinafine)

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection if you suffer from:

Impaired kidney function

As this medicine has not been tested in patients with kidney problems, please check with your doctor if you have any kidney problems

Take Special Care with **IROCAN:**

- **In the first 24 hours after administration of IROCAN**

During administration of **IROCAN** (30 – 90 minutes) and within 24 hours after administration you may experience some of the following symptoms:

- diarrhoea

- sweating

- abdominal pain

- watering eyes

- visual disturbance

- excessive mouth watering

The medical term for these symptoms is “acute cholinergic syndrome”. If you have any of these symptoms, immediately tell your doctor who will give you the treatment necessary.

- **From the day after treatment with IROCAN until next treatment**

During this period, you may experience various symptoms, which may be serious and require immediate treatment and close supervision.

Diarrhoea

If your diarrhoea starts more than 24 hours after administration of **IROCAN** (“delayed diarrhoea”) it may be serious. It is often seen about 5 days after administration. The diarrhoea should be treated immediately and kept under close supervision. Immediately after the first liquid stools do the following:

1. Take any antidiarrhoeal treatment that the doctor has given you, exactly as he/she has told you. The treatment must not be changed without consulting the doctor.
2. Drink large amounts of water and rehydration fluids, immediately (i.e. water, soda water, fizzy drinks, 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 hospital unit supervising the **IROCAN** treatment. It is very important that they are aware of the diarrhoea.

You must immediately tell the doctor, or the healthcare provider supervising the treatment, if:

- You have diarrhoea as well as fever (over 38 °C)
- You have severe diarrhoea (and vomiting) with excessive loss of water requiring intravenous hydration
- You still have diarrhoea 48 hours after starting the diarrhoea treatment

Note! Do not take any treatment for diarrhoea other than that given to you by your doctor and the fluids described above. Follow the doctor's instructions. The antidiarrhoeal treatment should not be used preventatively, even though you have experienced delayed diarrhoea at previous cycles.

Nausea and vomiting

If you have nausea and/or vomiting contact your doctor or the hospital unit immediately.

Neutropenia *(decrease in some white blood cells)*

IROCAN 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. Neutropenia is often seen during treatment with **IROCAN** and is reversible. Your doctor may arrange for you to have regular blood tests to monitor these white blood cells. If you have any fever (over 38°C) this may be an indication of infection associated with this neutropenia and requires immediate treatment. Therefore, if you have any fever, and particularly if you also have diarrhoea, contact your doctor or healthcare professional immediately, that they can give you the necessary treatment.

Breathing difficulties

If you have any breathing difficulties contact your doctor immediately.

Impaired liver function

Before treatment with **IROCAN** is started and before every following treatment cycle your doctor may monitor your liver function (by blood tests).

Heart problems

If you are at risk of having a heart attack your doctor may monitor you very carefully while you are given **IROCAN** and action should be taken to minimize the risk factors (e.g. smoking, high blood pressure, high levels of blood lipids).

Lowered resistance to Infections

Vaccination with a live or life-attenuated vaccine is not recommended in patients receiving **IROCAN**, because this might result in serious or fatal infections. Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.

Acute cholinergic syndrome

IROCAN may affect part of your nervous system that controls body secretions, leading to what is known as cholinergic syndrome. Symptoms can include runny nose, increased saliva, excess tears in the eyes, sweating, flushing, abdominal cramps, and diarrhoea. Let your healthcare provider know right away if you notice any of these symptoms, as there are medicines that can help control them.

Vascular disorders

IROCAN is associated with blood flow disorders (blood clots in the vessels of your legs and lungs) and it may occur rarely in patients with multiple risks factors.

Irradiation therapy

If you recently received treatment with pelvic or abdominal radiotherapy, you may be at increased risk of developing bone marrow suppression. Please talk to your health care provider before starting the **IROCAN**.

Chronic intestinal inflammation and/or intestinal blockage

Call your doctor if you have pain in your belly and you cannot have bowel movements, especially if you also have bloating and loss of appetite.

Others

IROCAN may cause sores in the mouth or on the lips, often within the first few weeks after starting treatment. This can cause mouth pain, bleeding, or even trouble eating. Your doctor or

nurse can suggest ways to reduce this, such as changing the way you eat or how you brush your teeth. If needed, your doctor can prescribe medicine to help with the pain.

Tell your doctor or dentist that you are on **IROCAN** if you are planning to have surgery or any procedure.

If used in combination with other anticancer medicines for your condition, please make sure that you also read the leaflets for the other medicine.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this **IROCAN** as it contains sorbitol**.** For

further information see **'IROCAN** contains sorbitol' below**.**

Children and adolescents:

IROCAN is not indicated for use in children

Other medicines and IROCAN:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The following medicines can alter the effects of **IROCAN**:

- Carbamazepine, phenobarbitone or phenytoin (medicines used for the treatment of epilepsy/seizures)
- Ketoconazole, itraconazole, voriconazole (medicines used to treat fungal infections)
- Rifampicin (used for the treatment of tuberculosis)
- Atazanavir sulphate (medicines used to treat HIV infection)
- The herbal medicine St John's Wort (Hypericum perforatum, a herbal dietary supplement used in the treatment of depression. This must not be used during and between treatments with **IROCAN** as it may decrease the effect of **IROCAN**
- Oral anticoagulants (used to reduce blood clotting and as a blood thinner) e.g. warfarin

- Yellow fever vaccine (**must not** be used while you are treated with **IROCAN**)
- Other live attenuated vaccines are also not recommended.
- **IROCAN** can cause serious diarrhoea. Try to avoid laxatives and stool softeners while taking this medicine.
- Clarithromycin, erythromycin and telithromycin (Medicines used to treat bacterial infection)
- Other medicines used for cancer therapy (antineoplastic medicines. When administered together with **IROCAN**, these medicines may worsen diarrhoea and blood disorders that may be experienced.
- A cortisone medicine known as dexamethasone used to treat inflammation and also cancer. When administered together with **IROCAN**, dexamethasone may enhance the chances of experiencing a decrease in a type of white blood cells (a blood disorder known as lymphocytopenia).
- Medicines that increase urination (diuretics) as this, together with the vomiting and diarrhoea may be experienced with **IROCAN**, can result in dehydration
- A cancer medicine known bevacizumab may increase the effects of **IROCAN**.
- St. John's Wort (a herbal medication used to treat depression). When administered together with **IROCAN**, the effect of **IROCAN** is reduced.

Pregnancy and 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] **IROCAN**.

- You should not be given **IROCAN** if you are pregnant.
- Women of child-bearing age should avoid becoming pregnant.
- Contraceptive measures must be taken by both male and female patients of reproductive age during and for at least three months after cessation of therapy. Still, if you become pregnant during this period you must immediately inform your doctor.

- You must not breast-feed while you are treated with **IROCAN**.
- No studies have been done, nevertheless, **IROCAN** may affect fertility. Talk with your doctor about the possible risk with **IROCAN** and the options that may preserve your ability to have children.

Driving and using machines

You may notice that you are dizzy and/or have trouble with your vision in the first couple of hours after you take **IROCAN**. Do not drive or operate machinery if you have this side effect.

IROCAN contains sorbitol:

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

IROCAN contains sorbitol and may have a laxative effect.

3. HOW TO TAKE IROCAN

Do not share medicines prescribed for you with any other person.

Always take IROCAN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with IROCAN will last. Do not stop treatment early because it will not have a positive effect on the disease. If you have the impression that the effect of IROCAN is too strong or too weak, tell your doctor or pharmacist.

IROCAN will be given to you by a healthcare professional. The solution is infused into the vein (as a drip).

IROCAN is for adults only.

Usual dose:

The amount of infusion you are given will depend on your age, size, weight 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 metres (m^2).

Treatment is continued as long as possible. If the cancer gets worse or the side effects are unacceptable, the treatment may be stopped.

If you receive more IROCAN than you should

Since a healthcare professional will administer **IROCAN**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

If you forget to receive IROCAN

Do not receive a double dose to make up for forgotten individual doses**.** Since a healthcare provider will administer **IROCAN,** it is unlikely that the dose will be missed.

If you stop taking IROCAN

Do not stop treatment early. Treatment is continued as long as possible. If the cancer gets worse or the side effects are unacceptable, the treatment may be stopped. The healthcare professional will take the necessary decisions when treatment is stopped.

4. POSSIBLE SIDE EFFECTS

IROCAN can have side effects.

Not all side-effects reported for IROCAN are included in this leaflet. Should your general health worsen while taking IROCAN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Shortness of breath, dry cough, and inspiratory crackles (crackles when taking a breath); early effects such as breathing difficulties.
- Allergic-reaction (skin rash including red itchy skin, urticaria, conjunctivitis, rhinitis).

- Severe allergic reactions causing swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (anaphylactic/ anaphylactoid reaction).
- Skin reactions.
- Reactions at the infusion site.
- Fever and infections.
- Delayed severe diarrhoea.
- Severe nausea and vomiting.
- Hair loss (the hair grows again after end of treatment).
- Severe transient acute cholinergic syndrome: the main symptoms are defined as early diarrhoea and various other symptoms such as abdominal pain; red, sore, itching or weeping eyes (conjunctivitis); running nose (rhinitis); low blood pressure; widening of the blood vessels (vasodilation); sweating; chills; a feeling of general discomfort and illness; dizziness; visual disturbances; pupil contraction; watering eyes and increased salivation, occurring during or within the first 24 hours after the infusion of **IROCAN**.
- Fever associated with a severe decrease in the number of a certain type of white blood cells (febrile neutropenia).
- Severe nausea and vomiting,
- Loss of water (dehydration), commonly associated with diarrhoea and /or vomiting.
- Constipation.
- Severe weakness (asthenia).

These are all very serious side effects. If you have them, you may have had a serious reaction to IROCAN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Constipation.
- Bleeding from the stomach.
- Abdominal pain and/or diarrhoea (a condition known as pseudomembranous colitis).
- Difficulty in passing urine (renal insufficiency), low blood pressure, dehydration associated with diarrhoea and/or vomiting.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Bruising or bleeding easily due to your body destroying its own blood platelets (peripheral thrombocytopaenia with antiplatelet antibodies).

Less frequent:

- Muscular contraction or cramps and numbness (paraesthesia).
- Inflammation of the large bowel causing abdominal pain (colitis, ischemic and ulcerative colitis).
- Intestinal perforation, loss of appetite (anorexia), abdominal pain, inflammation of the mucous membranes.
- Inflammation of the pancreas (pancreatitis) which may cause abdominal pain.
- Increased blood pressure during and following administration.
- Decreased levels of potassium and sodium in the blood, mostly related to diarrhoea and vomiting.
- Temporary speech disorders.
- Increase in levels of some digestive enzymes which break down sugars and fats.

Other side effects:

- Decreased number of a certain type of white blood cells (neutropenia) which increases the risk of infections.

- Decrease number of red blood cells (anaemia) which can make the skin pale and cause weakness and breathlessness.
- Decreased number of blood platelets (thrombocytopenia) which increases the risk of bruising and bleeding.

Laboratory tests:

- Transient and mild to moderate increase in serum levels of some liver enzymes (AST, ALT, alkaline phosphate) or bilirubin.
- Transient and mild to moderate increase in serum levels of some liver enzymes (transaminases, alkaline phosphatase) or bilirubin.
- Transient and mild to moderate increase of creatinine in the blood.
- Transient severe (grade 3) increase in serum levels of bilirubin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 **IROCAN.**

To contact Innovata Pharmaceuticals (Pty) Ltd.:

Email: regulatory@innovata.co.za

Tel: 086 999 0912

5. HOW TO STORE IROCAN

Single-dose vials of **IROCAN** 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 at or below 25 ºC or 4 days under refrigeration (2 – 8ºC).

Discard any unused portion thereafter. Do not freeze.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Any unused medicine or waste material should be returned to the pharmacy for destruction. Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IROCAN contains:

The active substance is irinotecan hydrochloride trihydrate.

The other ingredients are sorbitol, lactic acid, water for injection, sodium hydroxide, hydrochloric acid.

What IROCAN looks like and contents of the pack

Type 1 amber coloured glass vials containing a clear, slightly yellow solution.

IROCAN 40 mg/2 ml: Carton containing one single-dose type I amber glass vials of **IROCAN** 40 mg/2 ml.

IROCAN 100 mg/5 ml: Carton containing one single-dose, type I amber glass vials of **IROCAN** 100 mg/5ml.

IROCAN 300 mg/15 ml: Carton containing one single-dose, type I amber glass vials of **IROCAN** 300 mg/5 ml

IROCAN 500 mg/25 ml: Carton containing one single-dose, type I amber glass vials of **IROCAN** 500 mg/5 ml

Cap: Teflon lined chlorobutyl injection rubber stopper with an aluminium collar and a polypropylene flip-off seal

Holder of Certificate of Registration

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Access to the corresponding Professional information.

Access to the corresponding Professional Information is contained in the packaging or

Follow the link for the corresponding Professional Information for **IROCAN**: pi-pil-repository.innovata.co.za, alternatively, please scan the QR code below: