PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

IRINOTECAN 40 mg/2 ml FKSA

IRINOTECAN 100 mg/5 ml FKSA

IRINOTECAN 300 mg/15 ml FKSA

IRINOTECAN 500 mg/25 ml FKSA

concentrate for solution for infusion

Irinotecan hydrochloride

Contains a sugar alcohol (sorbitol) 45 mg/ml

Read all of this leaflet carefully before receiving IRINOTECAN FKSA

- 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.

What is in this leaflet

1. What IRINOTECAN FKSA is and what it is used for

IRINOTECAN FKSA is a cancer medication containing the active substance irinotecan hydrochloride, trihydrate that interferes with the growth of cancer cells and slows their growth and spread in the body.

IRINOTECAN FKSA is used to treat cancers of the colon and rectum. It may be given with other cancer

medicines in a combination chemotherapy.

2. What you need to know before you before you are given IRINOTECAN FKSA

IRINOTECAN FKSA should not be administered to you:

- If you are hypersensitive (have a history of allergic reactions) to irinotecan hydrochloride trihydrate or any of the other ingredients (see WHAT **IRINOTECAN FKSA** CONTAINS)
- If you are pregnant or breastfeeding
- If you have severe bone marrow disease
- If your general health status does not allow you to carry out general activities of daily living (WHO performance status higher than 2)
- If you have a disease involving frequent inflammation of the intestine (chronic inflammatory bowel disease) or blockage of the intestine (ileus).
- if your bilirubin level is higher than 1,5 times the upper limit of the normal range
- If you are a child below 18 years of age
- If you are taking St John's Wort (a herbal extract containing Hypericum) or ketoconazole.
- 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.

Warnings and precautions

IRINOTECAN FKSA will only be administered to you in a specialised unit where chemotherapy (cancer treatment) is administered and will only be administered by a qualified doctor (oncologist).

Tell your doctor or health care provider before being given the injection:

- If you have Gilbert's syndrome, an inherited condition that can cause elevated bilirubin levels and jaundice (yellow skin and eyes)

Special care should be taken with **IRINOTECAN FKSA:**

Diarrhoea

IRINOTECAN FKSA causes moderate to severe diarrhoea shortly after you receive your treatment and may also occur more than 24 hours after your treatment. If left untreated, it could lead to dehydration and

serious chemical imbalances, which can be life threatening.

You will have a higher risk of diarrhoea if you have had previous abdominal or pelvic radiotherapy.

Your doctor will prescribe medicines for diarrhoea to minimise fluid loss during your treatment.

Make sure you get the medicine right away, so that you will have it at home when you need it.

- Take these medicines exactly as prescribed by your doctor at the first sign of loose or frequent bowel movements.
- You should take lots of fluids (water, salty drink such as fizzy water, soda or soup) daily while being treated with **IRINOTECAN FKSA**
- If you experience fever, dehydration, light headedness, dizziness, faintness or diarrhoea more than 48 hours after anti-diarrhoeal treatment, contact your doctor as you may need to be hospitalised.

Neutropenia (decrease in some white blood cells)

Your doctor will monitor complete white blood cell counts and this should be performed during **IRINOTECAN FKSA** treatment. This can increase the risk of getting an infection. Be sure to let your doctor know right away if you have any signs of infection, such as fever (38 °C or higher), chills, pain when passing urine, a new cough, or bringing up sputum.

Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

Liver impairment

Liver function tests should be performed prior to your first treatment and before each cycle of treatment.

Your doctor will monitor the correct dosage of **IRINOTECAN FKSA** according to liver function.

Blood monitoring

Your doctor will likely test your blood before and during your treatment, to check for effects of the medicine on blood counts or on blood chemistry. Based on the test results, you may need medicines to help treat the effects. Your doctor may also need to reduce or delay your next dose of this medicine, or even stop it altogether. Keep all your appointments for doctor visits and lab tests.

This medicine may lower your platelet count in the weeks after it is given, which can increase your risk of bleeding. Speak with your doctor before taking any medicines or supplements that might affect your body's ability to stop bleeding, such as aspirin or aspirin-containing medicines, warfarin, or vitamin E.

Tell your doctor right away if you have unusual bruising, or bleeding such as nosebleeds, bleeding gums when you brush your teeth, or black, tarry stools.

Nausea and vomiting

You may have nausea and vomiting on the day you receive this medicine or in the first few days after. Your doctor will most likely prescribe anti-nausea medication before each cycle of treatment. Your doctor will likely prescribe anti-nausea medicines that you can take at home.

Have these medicines on hand for when you need them. Call your doctor if you are unable to take fluids by mouth due to nausea and vomiting.

Acute cholinergic syndrome

If you experience symptoms such as early diarrhoea and a group of symptoms such as runny nose, sweating, flushing abdominal cramping, excess tears in the eyes, narrowing of the pupils and increased saliva occur, you might be experiencing acute cholinergic syndrome, and your doctor will need to administer the correct dosages of atropine sulphate as treatment.

Lung disorders

Rarely, people on this medicine have serious lung problems. Tell your doctor right away if you have new or worsening cough, trouble breathing, and fever. Your doctor may need to stop your treatment to manage this problem.

This medicine may increase your risk of major blood clots in the veins of the legs or lungs, which can then travel to other parts of the body such as the lungs or brain. Tell your doctor right away if you notice chest pain, shortness of breath, or swelling, pain, redness, or warmth in an arm or leg.

Chronic intestinal inflammation and/or intestinal blockage

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

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 doctor before starting the **IRINOTECAN FKSA.**

Kidney function

Occurrences of kidney dysfunction have been reported. As **IRINOTECAN FKSA** may affect your kidney, it might be necessary to adjust the dosage. Your doctor will decide if this is necessary.

Cardiac disorders

Inform your doctor if you suffer/suffered from heart disease or if you previously received anticancer medicines. Your doctor will monitor you closely and discuss with you how risk factors (for example smoking,

high blood pressure and to high fat content) can be reduced.

As **IRINOTECAN FKSA** may affect your heart function, it might be necessary to adjust the dosage. Your doctor will decide if this is necessary.

Vascular disorders

IRINOTECAN FKSA is rarely 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.

Others

This medicine 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.

Contraception in women of childbearing potential/men & Breast-feeding

For contraception and breast-feeding information, refer to the information provided below under section pregnancy, breast-feeding and fertility.

Children and adolescents

The safety and efficacy of IRINOTECAN FKSA in children below 18 years of age have not been established.

Other medicines and IRINOTECAN FKSA

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

Tell your doctor if you are receiving or have received any of the following as some medicines may alter the effect of **IRINOTECAN FKSA**

- Medicines used to treat epilepsy/seizure (carbamazepine, phenobarbital and phenytoin)
- Medicines used to treat fungal infection ((ketoconazole, itraconazole, voriconazole and posaconazole)
- Medicines used to treat bacterial infection (clarithromycin, erythromycin and telithromycin)
- Medicines used to treat tuberculosis (rifampicin and rifabutin)
- The herbal medicine St John's Wort (Hypericum perforatum) may not be used concurrently with **IRINOTECAN FKSA** and not between treatments, as it may decrease the effect of **IRINOTECAN**

FKSA.

- Live attenuated vaccines
- Medicines used to treat HIV (indinavir, ritonavir, amprenavir, fosamprenavir, nelfinavir, atazanavir, and others)
- Medicines used to suppress your body's immune system to prevent transplant rejection (cyclosporine and tacrolimus)
- Medicines used to treat cancer (regorafenib, crizotinib and idelalisib). A cancer medicine known as bevacizumab may increase the effects of **IRINOTECAN FKSA**. When administered together with **IRINOTECAN FKSA**, 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 **IRINOTECAN FKSA**, dexamethasone may enhance the chances of experiencing a decrease in a type of white blood cells (a blood disorder known as lymphocytopenia).
- Medicines used to cause muscle paralysis/anaesthesia during surgery (neuromuscular blocking medicines). The effect of these medicines may be prolonged when administered together with **IRINOTECAN FKSA**
- Laxatives, as these 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 **IRINOTECAN FKSA**, can result in dehydration.
- Medicines used to treat epilepsy (i.e., anticonvulsants e.g., carbamazepine, phenobarbitone or phenytoin) decrease the effect of **IRINOTECAN FKSA**.
- Medicines used to treat fungal infection, known as azole antifungals (e.g., ketoconazole), as these may increase the effect of **IRINOTECAN FKSA**.
- Loperamide should not be taken in advance for the treatment of the diarrhoea side effect.
- anticoagulant (medicine that prevents clotting of blood).
- Cetuximab (an EGF receptor inhibitor)
- Medicines used to relax muscles used during general anaesthesia and surgery (suxamethonium)
- 5-fluorouracil/folinic acid
- Bevacizumab (an anticancer medicine)

- Cetuximab (an anticancer medicine)

Tell your doctor if you have had, or are due to have a yellow fever vaccination, or any other vaccinations (see "You should not be given **IRINOTECAN FKSA**")

If you require an operation, make sure your doctor and anaesthetist know that you are using **IRINOTECAN FKSA**, as it may alter the effect of some medicines used during surgery

This medicine can cause serious diarrhoea. Try to avoid laxatives and stool softeners while taking this medicine.

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.

Contraception

If you are a woman of childbearing age, then you have to use effective contraception during and up to 6 months after stopping treatment.

As a man, you have to use effective contraception during and up to 3 months after stopping treatment. It is important to check with your doctor about what kinds of birth control can be used with this medicine.

Pregnancy

This medicine may cause problems with the foetus if taken at the time of conception or during pregnancy. Men and women who are taking this medicine should use reliable birth control during treatment for at least three months (for males) and six months (for females). It is important to check with your doctor about what kinds of birth control can be used with this medicine.

Breastfeeding

Irinotecan and its metabolite were measured in human milk.

Breast-feeding should be discontinued for the duration of your treatment with this medicine.

If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

Fertility

No studies have been done, nevertheless, this medicine may affect fertility.

Talk with your doctor about the possible risk with this medicine and the options that may preserve your ability to have children.

Driving and using machines

It is not always possible to predict to what extent **IRINOTECAN FKSA** may interfere with the daily activities of a patient. Patients should ensure that they not engage in the above activities until they are aware of the measure to which **IRINOTECAN FKSA** affects them.

IRINOTECAN FKSA may cause dizziness and vision problems. Take care until you know how **IRINOTECAN FKSA** affects you before driving or operating any machinery.

IRINOTECAN FKSA contains sorbitol

Sorbitol is a source of fructose. If you have hereditary fructose intolerance (HFI), a rare genetic disorder, you 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 have HFI or no longer take sweet foods or drinks because you feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

IRINOTECAN FKSA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How IRINOTECAN FKSA is given to you

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

IRINOTECAN FKSA is for intravenous use only. Your doctor will decide on the suitable dose and duration of the treatment based on your specific condition and needs.

The amount of **IRINOTECAN FKSA** that you will receive depends on many factors, including your height and weight, your general health or other health problems, and the type of cancer or condition being treated. Your doctor will determine your dose and schedule.

IRINOTECAN FKSA is injected into a vein through an intravenous route (IV).

You will receive this injection in a clinic or hospital setting. **IRINOTECAN FKSA** must be given slowly, and the IV infusion can take up to 90 minutes to complete.

You may be given other medications to prevent nausea, vomiting, diarrhoea, and other side effects while

you are receiving **IRINOTECAN FKSA**. You may need to keep using these medicines for at least a day after your **IRINOTECAN FKSA** injection.

Tell your care givers if you feel any burning, pain, or swelling around the IV needle when **IRINOTECAN FKSA** is injected. If the medicine escapes from the vein it can cause tissue damage. If you experience pain or notice redness or swelling at the IV site while you are receiving **IRINOTECAN FKSA**, alert your healthcare professional immediately.

There are currently several treatment schedules recommended for **IRINOTECAN FKSA**. It is usually given either once every 3 weeks (**IRINOTECAN FKSA** given alone) or once every week **(IRINOTECAN FKSA** given in combination with 5FU/FA chemotherapy).

The dose will depend on a number of factors, including the treatment schedule, your body size, your age and general health, your blood counts, how well your liver is working, whether you have had radiation to your abdomen/pelvis, and whether you have any side effects such as diarrhoea.

If you receive more IRINOTECAN FKSA than you should

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

If you forget to use IRINOTECAN FKSA

IRINOTECAN FKSA is for intravenous use only.

Since a healthcare provider will administer **IRINOTECAN FKSA**, it is unlikely that the dose will be missed.

4. Possible side effects

IRINOTECAN FKSA can have side effects.

Not all side effects reported for **IRINOTECAN FKS**A are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **IRINOTECAN FKSA**, please consult your health care provider for advice.

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

- Signs of an allergic reaction: hives; difficult breathing; swelling of your face, lips, tongue, or throat.
- inflammation at the injection site

- inflammation of the lining of the mouth
- swelling of feet and hands, headache, increased sweating, flushing
- Fever
- Dehydration
- Early diarrhoea, more than 24 hours after you have received **IRINOTECAN FKSA**, accompanied by symptoms of increased salivation, watery eyes, sweating, flushing, abdominal cramping, chills, lacrimation (watery eyes), rhinitis (irritation and inflammation inside the nose which may result in stuffy nose, runny nose and/or post-nasal drip), dizziness, hypotension (low blood pressure), malaise (lack of well-being), myosis (constriction to the pupil of the eyes), conjunctivitis (inflammation of the eye), vasodilation (widening of blood vessels) (This can occur while the medicine is being administered. If so, alert your healthcare professional promptly. Medication can be given to stop and/or lessen this early side effect).
- Late diarrhoea, more than 48 hours after anti-diarrhoeal treatment. Because of concerns of dehydration and electrolyte imbalances with diarrhoea it is important to be in contact with health care professionals for monitoring, and for medication and diet modifications advice.
- Severe diarrhoea
- Nausea and Vomiting
- Decrease in white blood cells

IRINOTECAN FKSA 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.

If you have any fever this may be an indication of infection associated with this neutropenia.

These are all very serious side effects. If you have them, you may have had a serious reaction to **IRINOTECAN FKSA**. 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:

- Sweating
- Abdominal cramping
- Tears
- Narrowing of the pupils

- Increased of saliva in the mouth.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Blood problems including a change in the number of blood cells
    - Abnormally low number of white blood cells which could put you at increased risk for infection
    - Low number of red blood cells causing tiredness and shortness of breath
    - Low number of platelets (blood cells that help with clotting) which may cause bruising or bleeding
    - Low number of white blood cells with fever
- Transient speech disorders
- Sweating, chills, dizziness, fever
- Low blood pressure
- Diarrhoea, nausea, vomiting, dehydration
- Constipation
- Abdominal pain
- Hair loss (reversible)
- Muscle cramps
- Pain at the site where you have been injected
- Decreased appetite
- Cholinergic syndrome (see Take special care with **IRINOTECAN FKSA**)
- Inflammation of mucous membranes
- Feeling weak and having no energy
- Abnormal liver function test values
- Infection
- Abnormal kidney function test values (Poor function of the kidneys)

Less frequent side effects:

- Lung diseases
- High blood pressure

- Allergic reactions, such as itching or hives, any abnormal physical sensation and a tickling feeling
- Painful heart condition
- Extravasation which is leakage of medicine from the vein into the surrounding tissue, sign and symptoms include stinging burning sensation and oedema around the injection site
- Tumour-lysis syndrome which is when a large number of cancer cells die within a short period releasing their contents in the blood, sign and symptoms include nausea with or without vomiting, lack of appetite, fatigue, dark urine

Frequency unknown:

- Transient speech disorders during or shortly after treatment
- Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever) caused by bacteria called (Clostridium difficile)
- Blood infection
- Dehydration (due to diarrhoea and vomiting)
- Dizziness, rapid heart beat and pale skin (a condition called hypovolaemia
- Allergic reaction
- Pins and needles
- High blood pressure (during or after infusion)
- Heart problems*
- Lung disease causing wheezing and shortness of breath (see section 2)
- Hiccups
- Intestinal blockage
- Enlarged colon
- Bleeding from the bowels
- Inflammation of the large intestine
- Abnormal lab test results
- Hole in the intestine
- Fatty liver disease
- Skin reactions
- Reactions at the site where the medicine was administered

- Low level of potassium in the blood
- Low level of salt in the blood mostly related with diarrhoea and vomiting
- Muscle cramps
- Kidney problems*
- Low blood pressure *
- Fungal infections
- Viral Infections

* Infrequent cases of these events have been observed in patients who experienced episodes of dehydration associated with diarrhoea and/or vomiting, or infections of the blood.

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 nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) “Adverse Drug Reactions and Product Quality Reporting Form”, found on SAHPRA website: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **IRINOTECAN FKSA.**

5. How to store IRINOTECAN FKSA

Store all medicine out of reach of children.

Store at or below 25 °C. Do not freeze. Protect from light.

For intravenous use.

Single use only.

6. Contents of the pack and other information

What IRINOTECAN FKSA contains

The active substance is Irinotecan hydrochloride trihydrate

Each 1 ml contains 20 mg irinotecan hydrochloride trihydrate.

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

What IRINOTECAN FKSA looks like and contents of the pack

IRINOTECAN FKSA is a yellow coloured solution free from visible particles.

IRINOTECAN 40 mg/2 ml FKSA is packed into a 6 ml Type-I, amber, glass vial with a grey chlorobutyl rubber stopper and a 20 mm Aluminium flip-off over seal of green colour.

IRINOTECAN 100 mg/5 ml FKSA is packed into a 6 ml Type-I, amber, glass vial with a grey chlorobutyl rubber stopper and a 20 mm Aluminium flip-off over seal of blue colour.

IRINOTECAN 300 mg/15 ml FKSA is packed into a 20 ml Type-I, amber, glass vial with a grey chlorobutyl rubber stopper and a 20 mm Aluminium flip-off over seal of red colour.

IRINOTECAN 500 mg/25 ml FKSA is packed into a 30 ml, Type-I, amber, glass vial with a grey chlorobutyl rubber stopper and a 20 mm Aluminium flip-off over seal of yellow colour.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Ltd

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South Africa

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