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
2. What you need to know before you are given **IRINOTECAN FKSA**
3. How **IRINOTECAN FKSA** is given to you
4. Possible side effects
5. How to store **IRINOTECAN FKSA**
6. Contents of the pack and other information

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 FKSA** 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

Stand 7, Growthpoint Business Park,

162 Tonetti Street,

Halfway House, Extension 7, Midrand, 1685

South Africa

This leaflet was revised in:

06 November 2024

Registration numbers

IRINOTECAN 40 mg/2 ml FKSA: 45/26/0915

IRINOTECAN 100 mg/5 ml FKSA: 45/26/0916

IRINOTECAN 300 mg/15 ml FKSA: 45/26/0917

IRINOTECAN 500 mg/25 ml FKSA: 45/26/0918

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

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

konsentraat vir oplossing vir infusie

Irinotekaanhidrochloried

Bevat 'n suikeralkohol (sorbitol) 45 mg/ml

Lees hierdie hele inligtingsblad aandagtig deur voordat jy IRINOTECAN FKSA ontvang

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad

1. Wat is **IRINOTECAN FKSA** en waarvoor word dit gebruik
2. Wat jy moet weet voordat **IRINOTECAN FKSA** aan jou gegee word
3. Hoe **IRINOTECAN FKSA** aan jou gegee word
4. Moontlike newe-effekte
5. Hoe om **IRINOTECAN FKSA te bewaar**
6. Inhoud van die pakkie en ander inligting

2. Wat is IRINOTECAN FKSA en waarvoor word dit gebruik

IRINOTECAN FKSA is 'n kankermedisyne wat die aktiewe bestanddeel irinotekaanhidrochloriedtrihidraat bevat, wat die groei van kankerselle beïnvloed en hul groei en verspreiding in die liggaam vertraag.

IRINOTECAN FKSA word gebruik om kankers van die kolon en rektum te behandel. Dit kan saam met ander kankermedisyne in 'n kombinasie-chemoterapie gegee word.

2. Wat jy moet weet voordat IRINOTECAN FKSA aan jou gegee word

IRINOTECAN FKSA moet nie aan jou toegedien word nie:

- Indien jy hipersensitief is ('n geskiedenis van allergiese reaksies het) vir irinotekaanhidrochloriedtrihidraat of vir enige van die ander bestanddele (sien **WAT IRINOTECAN FKSA BEVAT**)
- Indien jy swanger is of borsvoed
- Indien jy erge beenmurgsiekte het
- Indien jou algemene gesondheidstoestand jou nie toelaat om normale daaglikse lewenstake uit te voer nie (WGO-prestasiestatus hoër as 2)
- Indien jy 'n siekte het wat gereelde inflammasie van die ingewande (chroniese inflammatoriese dermsiekte) of dermverstopping (ileus) veroorsaak
- indien jou bilirubienvlak hoër is as 1,5 keer die boonste limiet van die normale reikwydte
- Indien jy 'n kind onder 18 jaar oud is
- Indien jy Sint Janskruid ('n kruie-ekstrak wat Hypericum bevat) of ketokonasool neem
- indien jy tans of onlangs lewende verswakte entstowwe (entstowwe teen geelkoors, waterpokkies, gordelroos, masels, pampoentjies, rubella, tuberkulose, rotavirus, griep) ontvang of ontvang het, en dit moet ook nie vir 'n tydperk van 6 maande na staking van chemoterapie toegedien word nie.

Waarskuwings en voorsorgmaatreëls

IRINOTECAN FKSA sal slegs aan jou toegedien word in 'n gespesialiseerde eenheid waar chemoterapie (kankerbehandeling) toegedien word en dit sal slegs deur 'n gekwalifiseerde dokter (onkoloog) toegedien word.

Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:

- Indien jy Gilbert se sindroom het, 'n oorerflike toestand wat verhoogde bilirubienvlakke en geelsug (geel vel en oë) kan veroorsaak.

Wees versigtig met **IRINOTECAN FKSA:**

Diarree

IRINOTECAN FKSA veroorsaak matig-tot-ernstige diarree kort nadat jy jou behandeling ontvang het en dit kan ook meer as 24 uur na jou behandeling voorkom. Indien dit onbehandeld gelaat word, kan dit lei tot

dehidrasie en ernstige chemiese wanbalanse wat lewensgevaarlik kan wees.

Indien jy voorheen radioterapie van die buik of bekken gehad het, sal jy meer geneig wees om diarree te ontwikkel.

Jou dokter sal medisyne vir diarree voorskryf om vloeistofverlies tydens jou behandeling te verminder.

Maak seker jy kry die medisyne dadelik sodat jy dit by die huis het wanneer jy dit benodig.

- Neem hierdie medisyne presies soos jou dokter voorgeskryf het, by die eerste tekens van los of gereelde stoelgange.
- Jy moet daagliks baie vloeistowwe (water, souterige drankies soos gaskoeldrank, koeldrank of sop) inneem terwyl jy met **IRINOTECAN FKSA** behandel word.
- Indien jy meer as 48 uur na behandeling teen diarree koors, dehidrasie, lighoofdigheid, duiseligheid, floute of diarree ervaar, kontak asseblief jou dokter aangesien jy dalk gehospitaliseer moet word.

Neutropenie (afname in sommige witbloedselle)

Jou dokter sal jou totale witbloedseltelling nagaan en dit moet tydens behandeling met **IRINOTECAN FKSA** gedoen word. Dit kan die risiko om 'n infeksie te kry verhoog. Sorg dat jy jou dokter dadelik inlig indien jy enige tekens van infeksie opmerk, soos koors (38 °C of hoër), koue rillings, pynlike urinering, 'n nuwe hoes, of opwelling van sputum.

Vermy nabyheid aan siek mense of mense wat infeksies het. Lig jou dokter dadelik in indien jy tekens van infeksie ontwikkel.

Lewerinkorting

Lewerfunksiewaardes moet voor jou eerste behandeling en voor elke behandelingsiklus bepaal word. Jou dokter sal jou lewerfunksie monitor om die korrekte dosis van **IRINOTECAN FKSA** te bepaal.

Monitering van bloed

Jou dokter sal waarskynlik voor en tydens die behandeling bloedtoetse doen om te sien of die medisyne jou bloedtellings of bloedchemie beïnvloed. Gebaseer op die toetsresultate, kan jy moontlik medisyne benodig om die uitwerkings te help behandel. Jou dokter sal moontlik ook jou volgende dosis van hierdie medisyne moet verminder of uitstel, of dit selfs heeltemal staak. Hou alle afsprake vir doktersbesoeke en laboratoriumtoetse.

Hierdie medisyne kan jou bloedplaatjietelling verlaag in die weke nadat dit gegee is, wat jou risiko vir bloeding kan verhoog. Raadpleeg jou dokter voordat jy enige medisyne of aanvullings neem wat jou liggaam se vermoë kan beïnvloed om bloeding te stop, soos aspirien of aspirienbevattende medisyne,

warfarien of vitamien E bevat.

Lig jou dokter dadelik in as jy ongewone kneusings kry, of bloeding soos neusbloeding, bloeiende tandvleis wanneer jy jou tande borsel, of swart, teeragtige stoelgang.

Naarheid en braking

Jy kan dalk naarheid en braking ervaar op die dag wat jy hierdie medisyne ontvang of vir die eerste paar dae daarna. Jou dokter sal heel waarskynlik voor elke behandelingsiklus medisyne teen naarheid voorskryf. Jou dokter sal waarskynlik medisyne teen naarheid voorskryf om ook by die huis te neem.

Hou hierdie medisyne gereed vir ingeval jy dit nodig het. Bel jou dokter as jy weens naarheid en braking nie vloeistowwe per mond kan inneem nie.

Akute cholinergiese sindroom

Indien jy simptome soos vroeë diarree en 'n reeks simptome soos loopneus, sweet, blosing, buikkrampe, oormatige trane in die oë, vernouing van die pupille en verhoogde speekselafskeiding ervaar, kan jy akute cholinergiese sindroom hê en jou dokter sal die korrekte dosisse atropiensulfaat vir behandeling moet toedien.

Longversteurings

Dit is selde dat mense wat hierdie medisyne gebruik ernstige longprobleme ontwikkel. Kontak jou dokter dadelik as jy nuwe of verergerende hoes, moeilike asemhaling en koors ontwikkel. Jou dokter sal moontlik jou behandeling moet staak om hierdie probleem te behandel.

Hierdie medisyne kan jou risiko vir groot bloedklonte in die are van die bene of longe verhoog, wat dan na ander dele van die liggaam soos die longe of brein kan beweeg. Lig jou dokter dadelik in indien jy borskaspyn, kortasem, of swelling, pyn, rooiheid, of warmte in 'n arm of been opmerk.

Chroniese inwendige inflammasie en/of inwendige obstruksie

Kontak jou dokter as jy buikpyn het en jy kan nie 'n stoelgang passeer nie, veral as jy ook buikopsetting en verlies van eetlus het.

Bestralingsterapie

Indien jy onlangs behandeling met bekken- of abdominale radioterapie ontvang het, kan jy 'n groter risiko hê om beenmurgonderdrukking te ontwikkel. Praat asseblief met jou dokter voordat jy met die **IRINOTECAN FKSA begin.**

Nierfunksie

Voorvalle van nierdisfunksie is aangemeld. Aangesien **IRINOTECAN FKSA** jou niere kan beïnvloed, kan dit

nodig wees om die dosis aan te pas. Jou dokter sal besluit of dit nodig is.

Hartversteurings

Lig jou dokter in as jy aan hartsiekte ly/gely het of as jy voorheen medisyne teen kanker ontvang het. Jou dokter sal jou noukeurig monitor en met jou bespreek hoe die risikofaktore (bv. rook, hoë bloeddruk en oortollige vet) verminder kan word.

Aangesien **IRINOTECAN FKSA** jou hartfunksie kan beïnvloed, kan dit nodig wees om die dosis aan te pas. Jou dokter sal besluit of dit nodig is.

Vaskulêre versteurings

IRINOTECAN FKSA word selde geassosieer met bloedsomloopversteurings (bloedklonte in die vate van jou bene en longe) en kan in seldsame gevalle by pasiënte met verskeie risikofaktore voorkom.

Ander

Hierdie medisyne kan sere in die mond of op die lippe veroorsaak, dikwels binne die eerste paar weke nadat behandeling begin is. Dit kan mondpyn, bloeding of selfs probleme met eet veroorsaak. Jou dokter of verpleegster kan maniere voorstel om dit te verminder, soos om die manier waarop jy eet of hoe jy jou tande borsel te verander. Indien nodig, kan jou dokter medisyne vir die pyn voorskryf.

Voorbehoeding by vroue wat nog in hulle vrugbare jare is/mans & Borsvoeding

Vir inligting oor voorbehoeding en borsvoeding, sien asseblief die inligting hieronder in die afdeling vir swangerskap, borsvoeding en vrugbaarheid.

Kinders en adolessente

Die veiligheid en doeltreffendheid van IRINOTECAN FKSA is nog nie by kinders onder 18 jarige ouderdom bepaal nie.

Ander medisyne en IRINOTECAN FKSA

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Lig asseblief jou dokter in as jy enige van die volgende medisyne gebruik of geneem het, aangesien sommige medisyne die manier waarop **IRINOTECAN FKSA** werk kan beïnvloed

- Medisyne gebruik vir die behandeling van epilepsie/stuipe (karbamasepien, fenobarbitaal en fenitoïen)
- Medisyne gebruik vir die behandeling van fungusinfeksie (ketokonasool, itrakonasool, vorikonasool en

posakonasool)

- Medisyne gebruik vir die behandeling van bakteriële infeksie (klaritromisien, eritromisien en telitromisien)
- Medisyne gebruik vir die behandeling van tuberkulose (rifampisien en rifabutien)
- Die kruiemedisyne Sint Janskruid (*Hypericum perforatum*) mag nie gelyktydig met **IRINOTECAN FKSA** en nie tussen behandelings gebruik word nie, aangesien dit die effek van **IRINOTECAN FKSA** kan verminder
- Lewende verswakte entstowwe
- Medisyne gebruik vir die behandeling van MIV (indinavir, ritonavir, amprenavir, fosamprenavir, nelfinavir, atasanavir, en ander)
- Medisyne wat gebruik word om jou liggaam se immuunstelsel te onderdruk om verwerping van die oorplanting te voorkom (siklosporien en takrolimus)
- Medisyne gebruik vir die behandeling van kanker (regorafenib, krisotinib en idelalisib). 'n Kankermedisyne bekend as bevakisumab kan die uitwerking van **IRINOTECAN FKSA** verhoog. Wanneer hierdie medisyne saam met **IRINOTECAN FKSA** gegee word, kan dit die diarree en bloedafwykings wat mag voorkom vererger
- 'n Kortisoonmedisyne bekend as deksametasoon gebruik vir die behandeling van inflammasie en kanker. Wanneer dit op dieselfde tyd as **IRINOTECAN FKSA** gegee word, kan deksametasoon die kans op 'n afname in 'n sekere tipe witbloedsel ('n bloedversteuring bekend as limfositopenie) verhoog
- Medisyne wat gebruik word vir spierverlamming/narkose tydens 'n operasie (neuromuskulêre blokkerende medisyne). Die effek van hierdie medisyne kan verleng word wanneer dit saam met **IRINOTECAN FKSA** toegedien word
- Lakseermiddels, aangesien dit die voorkoms of erns van diarree kan vererger
- Medisyne wat urinering bevorder (diuretika) kan, tesame met die braking en diarree wat met **IRINOTECAN FKSA** kan voorkom, tot dehidrasie lei
- Medisyne gebruik vir die behandeling van epilepsie (d.w.s. stuipweermiddels, bv., karbamasepien, fenobarbitaal of fenitoïen) verminder die effek van **IRINOTECAN FKSA**
- Medisyne gebruik vir die behandeling van 'n swaminfeksie, genaamd asool-swamweermiddels (bv. ketokonasool), aangesien dit die effek van **IRINOTECAN FKSA** kan verhoog
- Loperamied moet nie vooraf geneem word om die newe-effek van diarree te behandel nie

- Antistolmiddels (medisyne wat die stolling van bloed voorkom)
- Setuksimab ('n EGF- reseptoriremmer)
- Medisyne vir spierverslapping tydens algemene narkose en chirurgie (suksametonium)
- 5-fluoorurasiel/foliniensuur
- Bevakisumab ('n antikankermedisyne)
- Setuksimab ('n antikankermedisyne)

Lig jou dokter in as jy 'n geelkoors-inenting of enige ander inentings gehad het of gaan kry (sien "**IRINOTECAN FKSA** moet nie aan jou toegedien word nie")

Indien jy 'n operasie benodig, sorg dat jou dokter en narkotiseur weet dat jy **IRINOTECAN FKSA** ontvang, aangesien dit die effek van sommige medisyne wat tydens die operasie gebruik word, kan verander

Hierdie medisyne kan ernstige diarree veroorsaak. Probeer om lakseermiddels en stoelversagmiddels te vermy terwyl jy hierdie medisyne gebruik.

Swangerskap en borsvoeding en vrugbaarheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne ontvang.

Voorbehoeding

Indien jy 'n vrou van vrugbare ouderdom is, moet jy doeltreffende voorbehoedmiddels gebruik, tydens en vir 6 maande nadat behandeling gestaak is.

As jy 'n man is moet jy doeltreffende voorbehoedmiddels gebruik, tydens en tot 3 maande nadat behandeling gestaak is. Dit is belangrik om met jou dokter te kontroleer watter tipes geboortebeperking met hierdie medisyne gebruik kan word.

Swangerskap

Hierdie medisyne kan probleme met die fetus veroorsaak as dit tydens bevrugting of tydens die swangerskap gebruik word. Mans en vroue wat hierdie medisyne gebruik, moet betroubare kontrasepsie vir ten minste drie maande (vir mans) en ses maande (vir vroue) tydens behandeling gebruik. Dit is belangrik om met jou dokter te kontroleer watter tipes geboortebeperking met hierdie medisyne gebruik kan word.

Borsvoeding

Irinotekaan en sy metaboliet is in mensmelk waargeneem.

Borsvoeding moet vir die duur van jou behandeling met hierdie medisyne gestaak word.

Indien jy borsvoed, vra jou dokter of apteker om raad voordat jy hierdie medisyne neem.

Vrugbaarheid

Geen studies is gedoen nie, nietemin kan hierdie medisyne vrugbaarheid beïnvloed.

Bespreek met jou dokter die moontlike risiko's van hierdie medisyne en die opsies om jou vermoë om kinders te hê te bewaar.

Bestuur en die gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel tot hoe 'n mate **IRINOTECAN FKSA** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle nie bewus is tot hoe 'n mate **IRINOTECAN FKSA** hulle aantas nie.

IRINOTECAN FKSA kan duiseligheid en probleme met sig veroorsaak, Wees versigtig totdat jy weet hoe **IRINOTECAN FKSA** jou raak voordat jy bestuur of enige masjinerie hanteer.

IRINOTECAN FKSA bevat sorbitol

Sorbitol is 'n bron van fruktose. Indien jy 'n oorerflike fruktose-onverdraagsaamheid (HFI), 'n seldsame genetiese afwyking, het moet jy nie hierdie medisyne ontvang nie. Pasiënte met HFI kan nie fruktose afbreek nie, wat ernstige newe-effekte kan veroorsaak.

Jy moet jou dokter inlig voordat jy hierdie medisyne ontvang as jy HFI het of nie meer soet kos of vloeistowwe kan inneem nie omdat jy naar voel, opbring of onaangename effekte ervaar soos buikopsetting, maagkrampe of diarree.

IRINOTECAN FKSA bevat natrium

Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per dosis, dit wil sê dit is in wese 'natriumvry'.

3. Hoe IRINOTECAN FKSA aan jou gegee word

Daar sal nie van jou verwag word om **IRINOTECAN FKSA** aan jouself toe te dien nie. Dit sal deur 'n gekwalifiseerde persoon aan jou gegee word.

IRINOTECAN FKSA is slegs vir intraveneuse gebruik. Jou dokter sal op grond van jou spesifieke siektetoestand en behoeftes besluit oor 'n geskikte dosis en duur van die behandeling.

Die hoeveelheid **IRINOTECAN FKSA** wat jy sal ontvang, hang van baie faktore af, insluitend jou lengte en

gewig, jou algemene gesondheid of ander gesondheidsprobleme, die tipe kanker of siektetoestand wat behandel word. Jou dokter sal jou dosis en skedule bepaal.

IRINOTECAN FKSA word in 'n aar, deur 'n intraveneuse roete (IV), ingespuit.

Jy sal hierdie inspuiting in 'n kliniek of hospitaalomgewing ontvang. **IRINOTECAN FKSA** moet stadig gegee word, en die IV infusie kan tot en met 90 minute duur om af te handel.

Jy kan moontlik ander medisyne ontvang om naarheid, braking, diarree en ander newe-effekte te voorkom terwyl jy **IRINOTECAN FKSA** ontvang. Jy sal dalk moet aanhou om hierdie medisyne vir ten minste 'n dag ná jou **IRINOTECAN FKSA**-inspuiting te gebruik.

Lig jou verpleegster in as jy brand, pyn of swelling rondom die IV-naald ervaar wanneer **IRINOTECAN FKSA** ingespuit word. Indien die medisyne uit die aar lek kan dit weefselskade veroorsaak. Indien jy pyn of rooiheid of swelling ervaar by die IV-plek terwyl jy **IRINOTECAN FKSA** ontvang, lig dadelik jou gesondheidsorgkundige in.

Daar is tans verskeie behandelingskedules wat aanbeveel word vir **IRINOTECAN FKSA**. Dit word gewoonlik een keer elke 3 weke gegee (**IRINOTECAN FKSA** alleen gegee) of een keer elke week (**IRINOTECAN FKSA** gegee in kombinasie met 5FU/FA-chemoterapie).

Die dosis sal afhang van 'n aantal faktore, insluitend die behandelingskedule, jou liggaamsgrootte, jou ouderdom en algemene gesondheid, jou bloedtellings, hoe goed jou lewer werk, of jy bestraling op jou buik/bekken gehad het, en of jy enige newe-effekte soos diarree het.

Indien jy meer IRINOTECAN FKSA ontvang het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer **IRINOTECAN FKSA** sal toedien, sal hy/sy die dosis beheer. Ingeval daar egter 'n oordosering is, sal jou dokter die nodige doen om dit te hanteer.

Indien jy vergeet om IRINOTECAN FKSA te gebruik

IRINOTECAN FKSA is slegs vir intraveneuse gebruik.

Aangesien 'n gesondheidsorgverskaffer **IRINOTECAN FKSA** sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

IRINOTECAN FKSA kan newe-effekte hê.

Nie alle newe-effekte wat vir **IRINOTECAN FKSA** aangemeld is, is by hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid verswak of jy enige ongewenste effekte ervaar wanneer jy **IRINOTECAN FKSA** ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Tekens van 'n allergiese reaksies: netelroos; moeilike asemhaling; swelling van jou gesig, lippe, tong of keel
- inflammasie by die plek van inspuiting
- inflammasie van die slymvliesvoering in die mond
- swelling van die voete en hande, hoofpyn, sweet meer, gloede
- Koors
- Dehidrasie
- Vroeë diarree, meer as 24 uur nadat jy **IRINOTECAN FKSA** ontvang het, gepaardgaande met simptome van verhoogde speekselafskeiding, waterige oë, sweet, gloede, buikkrampe, kouekoors, traanafskeiding (waterige oë), rinitis (irritasie en ontsteking in die neus wat kan lei tot 'n verstopte neus, loopneus en/of postnasale drup), duiseligheid, hipotensie (lae bloeddruk), malaise (ongesteldheid), miose (konstriksie van die pupille van die oë), konjunktivitis (oogontsteking), vasodilatasie (verwyding van die bloedvate). (Dit kan voorkom terwyl die medisyne toegedien word. In hierdie geval, lig dadelik jou gesondheidsorgkundige in. Medisyne kan gegee word om hierdie vroeë newe-effek te stop en/of te verminder)
- Laat diarree, meer as 48 uur na behandeling teen diarree. Weens kommer oor dehidrasie en elektrolietwanbalans met diarree, is dit belangrik om in kontak te bly met gesondheidsorgkundiges vir monitering en raad oor medisyne en dieetaanpassings
- Erge diarree
- Naarheid en braking
- Afname in witbloedselle

IRINOTECAN FKSA kan 'n afname in die aantal witbloedselle, wat 'n belangrike rol speel om infeksies te beveg, veroorsaak. Dit is bekend as neutropenie.

Indien jy enigsins koors het, kan dit 'n aanduiding wees van infeksie wat met hierdie neutropenie geassosieer word.

Al hierdie newe-effekte is baie ernstig. Indien jy enige daarvan ervaar, kan jy moontlik 'n ernstige reaksie op op **IRINOTECAN FKSA** hê. Jy kan dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter dadelik in, of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy die volgende waarneem:

- Sweet
- Buikkrampe
- Trane
- Vernoude pupille
- Verhoogde speekselvorming in mond.

Al hierdie newe-effekte is baie ernstig. Jy kan dringende mediese aandag benodig.

Lig jou dokter in as jy enige van die volgende waarneem:

Gereelde newe-effekte:

- Bloedafwykings, insluitend 'n verandering in die aantal bloedselle
    - Abnormale lae aantal witbloedselle, wat jou aan 'n hoër risiko vir infeksie kan blootstel
    - Lae aantal rooibloedselle wat moegheid en kortasem veroorsaak
    - Lae aantal plaatjies (bloedselle wat help met stolling) wat kneusing of bloeding kan meebring
    - Lae aantal witbloedselle met koors
- Verbygaande spraakversteurings
- Sweet, kouekoors, duiseligheid, koors
- Lae bloeddruk
- Diarree, naarheid, braking, dehidrasie
- Hardlywigheid
- Buikpyn
- Haarverlies (omkeerbaar)
- Spierkrampe
- Pyn by die plek waar jy ingespuit was
- Afname in eetlus
- Cholinergiese sindroom (sien Wees versigtig met **IRINOTECAN FKSA**)
- Inflammasie van die slymvliese
- Voel swak en sonder energie

- Abnormale lewerfunksiewaardes
- Infeksie
- Abnormale nierfunksiewaardes (swak funksionering van die niere)

Minder gereelde newe-effekte:

- Longsiekte
- Hoë bloeddruk
- Allergiese reaksies, soos jeuk of netelroos, 'n abnormale fisiese sensasie en 'n prikkelgevoel
- Pynlike hartaandoening
- Ekstravasasie, dit is die uitlek van medisyne uit die aar in die omliggende weefsel. Tekens en simptome sluit in 'n brandgevoel en edeem rondom die inspuitplek
- Tumorlisesindroom, waarby 'n groot aantal kankerselle binne 'n kort tydperk sterf en hul inhoud in die bloed vrystel. Tekens en simptome sluit in naarheid met of sonder braking, gebrek aan eetlus, moegheid, donker urien.

Frekwensie onbekend:

- Verbygaande spraakafwykings tydens of kort na die behandeling
- Erge, aanhoudende of bloederige diarree (wat met maagpyn of koors geassosieer kan word) wat deur bakterieë (*Clostridium difficile*) veroorsaak word
- Bloedinfeksie
- Dehidrasie (weens diarree en braking)
- Duiseligheid, vinnige hartslag en bleek vel ('n toestand genaamd hipovolemie)
- Allergiese reaksie
- Speld-en-naaldprikkels
- Hoë bloeddruk (tydens of na infusie)
- Hartprobleme*
- Longsiekte wat hyging en kortasem veroorsaak (sien afdeling 2)
- Hik
- Inwendige obstruksie
- Vergrote kolon
- Bloeding uit die dermkanaal

- Inflammasie van die dikderm
- Abnormale laboratoriumtoetsresultate
- Gat in die derm
- Vetterige lewersiekte
- Velreaksies
- Reaksies by die plek waar die medisyne toegedien was
- Lae bloedkaliumvlak
- Lae bloedsoutvlak, meestal te wyte aan diarree en braking
- Spierkrampe
- Nierprobleme*
- Lae bloeddruk*
- Swaminfeksies
- Virusinfeksies

* Seldsame gevalle van hierdie voorvalle was by pasiënte waargeneem wat episodes van dehidrasie ervaar het wat met diarree en/of braking of bloedinfeksies geassosieer word.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingsblad vermeld word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, praat met jou dokter of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) “Adverse Drug Reactions and Product Quality Reporting Form”, op die SAHPRA webwerf: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van **IRINOTECAN FKSA** te verskaf.

5. Hoe om IRINOTECAN FKSA te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C. Moenie vries nie. Beskerm teen lig.

Slegs vir intraveneuse gebruik.

Slegs vir enkelgebruik.

6. Inhoud van die pakkie en ander inligting

Wat IRINOTECAN FKSA bevat

Die aktiewe bestanddeel is irinotekaanhidrochloriedtrihidraat.

Elke 1 ml bevat 20 mg irinotekaanhidrochloriedtrihidraat.

Die ander bestanddele is sorbitol, melksuur, natriumhidroksied en water vir inspuiting.

Hoe IRINOTECAN FKSA lyk en inhoud van die pakkie

IRINOTEC**AN FKSA** is 'n geelkleurige oplossing sonder sigbare deeltjies.

IRINOTECAN 40 mg/2 ml FKSA word verpak in 'n 6 ml amber Tipe I glasflessie met 'n grys chloorbutielrubberprop en 'n groenkleurige 20 mm aluminium wip-af seël.

IRINOTECAN 100 mg/5 ml FKSA word verpak in 'n 6 ml amber Tipe I glasflessie met 'n grys chloorbutielrubberprop en 'n bloukleurige 20 mm aluminium wip-af seël.

IRINOTECAN 300 mg/15 ml FKSA word verpak in 'n 20 ml amber Tipe I glasflessie met 'n grys chloorbutielrubberprop en 'n rooikleurige 20 mm aluminium wip-af seël.

IRINOTECAN 500 mg/25 ml FKSA word verpak in 'n 30 ml amber Tipe I glasflessie met 'n grys chloorbutielrubberprop en 'n geelkleurige 20 mm aluminium wip-af seël.

Houer van die Registrasiesertifikaat

Fresenius Kabi South Africa (Pty) Ltd

Erf 7, Growthpoint Business Park,

Tonettistraat 162

Halfway House, Extension 7, Midrand, 1685

Suid-Afrika

Hierdie inligtingsblad was voorheen hersien op:

06 November 2024

Registrasienommers

IRINOTECAN 40 mg/2 ml FKSA: 45/26/0915

IRINOTECAN 100 mg/5 ml FKSA: 45/26/0916

IRINOTECAN 300 mg/15 ml FKSA: 45/26/0917

IRINOTECAN 500 mg/25 ml FKSA: 45/26/0918