Patient Information Leaflet for FLUCONAZOLE 2 mg/mL FRESENIUS

SCHEDULING STATUS: S4

FLUCONAZOLE 2 mg/mL FRESENIUS solution for infusion

Fluconazole

Sugar free.

Read all of this leaflet carefully before you are given FLUCONAZOLE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

1. What FLUCONAZOLE FRESENIUS is and what it is used for

FLUCONAZOLE FRESENIUS is a medicine for the treatment and prevention of infections with fungi.

FLUCONAZOLE FRESENIUS belongs to a group of medicines active against infections with fungi, called imidazoles.

2. What you need to know before you are given FLUCONAZOLE FRESENIUS

FLUCONAZOLE FRESENIUS should not be given to you:

- if you are allergic (hypersensitive) to fluconazole, or other similar medicines such as ketoconazole and itraconazole or to any of the other ingredients of FLUCONAZOLE FRESENIUS (listed in section 6)
- in multiple doses of 400 mg per day or higher if you are also taking terfenadine (an antihistamine for allergies)
- if you are taking medicines known to affect your heart and that affect the way your body handles FLUCONAZOLE FRESENIUS, such as:
    - cisapride (used to treat heartburn and to lower stomach acid)
    - astemizole (an antihistamine for allergies)
    - erythromycin (an antibiotic)
    - pimozide (a so-called neuroleptic used to treat mental illness)
    - quinidine (used in the treatment of heart rhythm disorders)
- if you are pregnant or breastfeeding your infant.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with FLUCONAZOLE FRESENIUS:

- if you have *tinea capitis* (ringworm, a fungal infection of the scalp)
- if you have cryptococcosis (a fungal injection of the lungs or skin)
- if you have kidney disease
- if you have problems with your adrenal glands which produce certain hormones in the body
- if you have currently, or have previously had, problems with your liver
- if you have AIDS or have an infection that affects your whole body. If you have this, you may be more prone to serious skin reactions. Tell your doctor immediately if you develop skin rashes, hives or skin peeling

- if you are taking other medicines that work similar to FLUCONAZOLE FRESENIUS in the body (see "**Other medicines and FLUCONAZOLE FRESENIUS**")
- if you have porphyria (a rare hereditary disease in which the blood pigment haemoglobin is abnormally metabolised)
- if you have heart disease including heart rhythm problems and/or electrolyte abnormalities such as low potassium levels in your blood.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop using FLUCONAZOLE FRESENIUS and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and FLUCONAZOLE FRESENIUS

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

The effect of treatment can be affected if FLUCONAZOLE FRESENIUS is used at the same time as certain other medicines. Please tell your doctor or other healthcare provider if you are taking or using any of the following medicines:

- **Abrocitinib** (used to treat atopic dermatitis, also known as atopic eczema).
- **Alfentanil** (a strong painkiller).
- **Amiodarone** (for irregular heartbeat).
- **Amitriptyline, nortriptyline** (used for the treatment of depression).
- **Amphotericin B** (used in the treatment of fungal infections).
- **Astemizole** (an antihistamine for allergies) (see "**FLUCONAZOLE FRESENIUS should not be given to you"**).
- **Benzodiazepines such** as midazolam or triazolam (certain sleeping pills).

- **Calcium channel blockers** such as nifedipine, isradipine, verapamil, nicardipine, amlodipine, felodipine (used in the treatment of heart rhythm disorders and high blood pressure).
- **Carbamazepine** (used in the treatment of epilepsy).
- **Celecoxib** (used in the treatment of inflammation).
- **Ciclosporin** (used in organ transplantation).
- **Cisapride** (used to treat heartburn and to lower stomach acid) (see "**FLUCONAZOLE FRESENIUS should not be given to you"**).
- **Cyclophosphamide** (used to treat several types of cancer).
- **Didanosine** (used in the treatment of HIV/AIDS).
- **Erythromycin** (an antibiotic) (see "**FLUCONAZOLE FRESENIUS should not be given to you**").
- **Everolimus** (used to treat several types of cancer and in organ transplantation).
- **Fentanyl** (used for serious pain).
- **Halofantrine** (used to treat malaria).
- **HMG-CoA reductase inhibitors (so-called statins)** such as atorvastatin, simvastatin, fluvastatin (medicines that lower blood lipids).
- **Hydrochlorothiazide** (used to increase the flow of urine, a diuretic).
- **Ibrutinib** (used to treat certain types of cancer).
- **Isoniazid** (used in the treatment of tuberculosis ("TB")).
- **Ivacaftor** (alone or in combination with other medicines used for treating cystic fibrosis).
- **Losartan** (used in the treatment of high blood pressure).
- **Lurasidone** (used to treat schizophrenia).
- Medicines used to treat epilepsy in general.
- **Methadone** (a painkiller, opioid).
- **Midazolam, triazolam** (used to help you sleep or for anxiety).
- **Nevirapine** (for treatment of HIV/AIDS).

- **NSAIDs** (nonsteroidal anti-inflammatory drugs), such as flurbiprofen, ibuprofen, naproxen, lornoxicam, meloxicam, diclofenac (used to treat pain, inflammation and fever).
- **Olaparib** (used to treat certain types of cancer).
- **Oral contraceptives** (the pill – to prevent pregnancy).
- **Phenytoin** (used to control epilepsy).
- **Pimozide** (a so-called neuroleptic medicine, used to treat mental illness) (see "**FLUCONAZOLE FRESENIUS should not be given to you**").
- **Prednisone** or other steroid therapies (cortisone-like medicines used in inflammation and organ transplants).
- **Quinidine** (a medicine used for irregular heartbeat) (see "**FLUCONAZOLE FRESENIUS should not be given to you**").
- **Rifampicin or rifabutin** (used in the treatment of tuberculosis and other infections).
- **Saquinavir** (for treatment of HIV/AIDS).
- **Sirolimus** (used in organ transplantation).
- **Sulphonylureas** such as chlorpropamide, glibenclamide, glipizide or tolbutamide (used to control diabetes).
- **Tacrolimus** (used in organ transplantation).
- **Terfenadine** (an antihistamine for allergies) (see "**FLUCONAZOLE FRESENIUS should not be given to you**").
- **Theophylline** (used to control asthma) and medicines related to theophylline called xanthine bases.
- **Tofacitinib** (used to treat certain types of arthritis, and ulcers in the colon).
- **Tolvaptan** (used to increase the flow of urine, a diuretic).
- **Trimetrexate** (used in the treatment of pneumonia).
- **Vinca alkaloids** such as vincristine and vinblastine (used to treat certain types of cancer).
- **Vitamin A** (to treat acne).
- **Voriconazole** (used in the treatment of fungal infections).

- **Warfarin** and other coumarin or indanedione type medicines (blood thinning medicines).
- **Zidovudine** (for treatment of HIV/AIDS).

Pregnancy and breastfeeding

FLUCONAZOLE FRESENIUS must not be given to you if you are pregnant or breastfeeding your baby (see "FLUCONAZOLE FRESENIUS should not be given to you").

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.
For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

FLUCONAZOLE FRESENIUS may increase the risk of miscarriage if given during the first or second trimester of pregnancy. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the heart**,** bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

FLUCONAZOLE FRESENIUS is present in breastmilk; you should not receive FLUCONAZOLE FRESENIUS if you are breastfeeding your baby.

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 healthcare provider for advice before FLUCONAZOLE FRESENIUS is given to you.

Driving and using machines

It should be borne in mind that dizziness or fits can occasionally occur in people receiving FLUCONAZOLE FRESENIUS so care should be taken when driving or operating machinery (see "**Possible side effects**").

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

FLUCONAZOLE FRESENIUS contains sodium

FLUCONAZOLE FRESENIUS contains salt (sodium chloride).

If you are on a low sodium (salt) diet tell your doctor or other healthcare provider before they give you FLUCONAZOLE FRESENIUS.

FLUCONAZOLE FRESENIUS contains 3,5 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0,175 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How FLUCONAZOLE FRESENIUS will be given

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

FLUCONAZOLE FRESENIUS will be administered to you via a drip (slow injection into a vein).

The dose will be determined by your doctor.

Treatment will normally continue until the infection has gone.

Patients with kidney problems

Your doctor will adjust the dose based on your kidney function.

Children

Your doctor will determine the dose in children.

If you receive more FLUCONAZOLE FRESENIUS than you should:

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

If you are worried you have been given too much or have any questions about the dose talk to your doctor or other healthcare provider.

If you forget to receive FLUCONAZOLE FRESENIUS

Since a healthcare provider will administer FLUCONAZOLE FRESENIUS, it is unlikely that the dose will be missed.

If you think you have missed a dose speak to your doctor or other healthcare provider.

If you have any further questions ask your doctor or other healthcare provider.

4. Possible side effects

FLUCONAZOLE FRESENIUS can have side effects.

Not all side effects reported for FLUCONAZOLE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FLUCONAZOLE FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving FLUCONAZOLE FRESENIUS and tell your doctor immediately:

- A sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure.
- Swelling of the face, lips, tongue and windpipe with wheezing and difficulty in breathing.
- Severe, extensive, blistering skin rash, with peeling of skin.
- Seizures or fits (convulsions).

- Liver problems and toxicity causing abnormal weakness, loss of appetite, persistent nausea, vomiting and/or jaundice (where the skin, white of the eyes and inside of the mouth turn yellow).
- Decrease in the number of cells in the circulation that may lead to anaemia, increased susceptibility to infection, easy bruising or bleeding.
- Infection with symptoms of fever and a severe worsening of your general condition, or fever with local infection e.g. sore throat, pharynx (back of throat), mouth or urinary tract problems.
- Changes in heart rhythm.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Skin rash.
- Feeling sick (nausea).
- Being sick (vomiting).
- Stomach ache or pain.
- Diarrhoea.
- Alterations in blood test results of liver function.

Less frequent side effects:

- Changes in how food tastes, dry mouth.
- Dizziness.
- Indigestion.
- Wind (flatulence).
- Loss of appetite.

- Itching or rash, wheals, swelling or blistering (hives).
- Increased sweating.
- Loss of appetite.
- Changes in blood test results of kidney function.
- Abnormal sleep (sleeplessness, drowsiness).
- Numbness, trembling.
- Pain in muscles.
- Feeling weak and tired.
- Fever.
- Increased levels of fats in the blood (cholesterol and triglycerides).
- Decreased levels of potassium leading to weakness and an irregular or fast heart beat.
- Hair loss (alopecia).

Side effects with an unknown frequency:

- Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS).

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, 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 FLUCONAZOLE FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-

kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store FLUCONAZOLE FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Keep the product in the outer container until required for use.

Do not use FLUCONAZOLE FRESENIUS after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

The product must be used immediately after first opening the container.

Use only if the solution is clear and free from visible particles. Do not use if the bottle is damaged.

The bottles are for single use only. Once having been used, bottles and any remaining contents must be disposed of.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What FLUCONAZOLE FRESENIUS contains

The active substance is fluconazole. 1 mL solution for infusion contains 2 mg of fluconazole.

One bottle with 50 mL FLUCONAZOLE FRESENIUS solution for infusion contains 100 mg of fluconazole.

One bottle with 100 mL FLUCONAZOLE FRESENIUS solution for infusion contains 200 mg of fluconazole.

One bottle with 200 mL FLUCONAZOLE FRESENIUS solution for infusion contains 400 mg of fluconazole.

The other ingredients are sodium chloride, water for injection, hydrochloric acid or sodium hydroxide (for pH-adjustment).

Sugar free.

What FLUCONAZOLE FRESENIUS looks like and contents of the pack

A clear to almost colourless sterile solution in clear transparent bottlepack polyethylene (KabiPac) containers packed in 50 mL; 100 mL and 200 mL bottles.

50 mL solution filled in 100 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.
100 mL solution filled in 100 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.
200 mL solution filled in 250 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.

Pack sizes of 1, 10; 20; 25; 30; 40 or 60 bottles.
Not all listed container sizes and pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

Pasiëntinligtingsblad vir FLUCONAZOLE 2 mg/mL FRESENIUS

SKEDULERINGSTATUS: S4

FLUCONAZOLE 2 mg/mL FRESENIUS oplossing vir infusie

Flukonasool

Suikervry.

Lees die hele inligtingsblad aandagtig deur voordat FLUCONAZOLE FRESENIUS aan jou gegee word

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

1. Wat is FLUCONAZOLE FRESENIUS en waarvoor word dit gebruik

FLUCONAZOLE FRESENIUS is 'n medisyne vir die behandeling en voorkoming van swaminfeksies.

FLUCONAZOLE FRESENIUS behoort tot 'n groep medisyne genaamd imidasole, wat aktief is teen swaminfeksies.

2. Wat jy moet weet voordat FLUCONAZOLE FRESENIUS aan jou gegee word

Jy moet nie FLUCONAZOLE FRESENIUS ontvang nie:

- indien jy allergies (hipersensitief) is vir flukonasool of ander soortgelyke medisyne soos ketokonasool en itrakonasool, of vir enige van die ander bestanddele van FLUCONAZOLE FRESENIUS (gelys in afdeling 6)
- indien dit in veelvuldige dosisse van 400 mg per dag of meer is, as jy ook terfenadien ('n antihistamien vir allergieë) neem
- indien jy medisyne neem met ’n bekende invloed op jou hart en wat die manier waarop jou liggaam FLUCONAZOLE FRESENIUS hanteer, beïnvloed, soos:
    - sisapried (gebruik vir die behandeling van sooibrand en om maagsuur te verminder)
    - astemisool ('n antihistamien vir allergieë)
    - eritromisien ('n antibiotikum)
    - pimosied ('n sogenaamde neuroleptikum gebruik vir die behandeling van geestesteuring)
    - kinidien (gebruik vir die behandeling van hartritmeversteurings)
- indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat jy die inspuiting ontvang:

Wees veral versigtig vir FLUCONAZOLE FRESENIUS:

- indien jy *tinea capitis* het (omlope, 'n swaminfeksie van die kopvel)
- indien jy kriptokokkokose het ('n swaminfeksie van die longe of die vel)
- indien jy niersiekte het
- indien jy probleme het met jou byniere, wat sekere hormone in die liggaam vervaardig
- indien jy tans probleme met jou lewer het, of voorheen gehad het

- indien jy VIGS het, of 'n infeksie wat jou hele liggaam aantas. Indien jy dit het, kan jy meer geneig wees tot ernstige velreaksies. Lig jou dokter onmiddellik in indien jy veluitslag, netelroos of velafskilfering ontwikkel
- indien jy ander medisyne gebruik wat op dieselfde manier as FLUCONAZOLE FRESENIUS in die liggaam werk (sien "**Ander medisyne en FLUCONAZOLE FRESENIUS**")
- indien jy aan porfirie ly ('n seldsame oorerflike siekte waarby die bloedpigment hemoglobien abnormaal gemetaboliseer word)
- indien jy aan hartsiektes ly, insluitend onreëlmatige hartritme en/of elektrolietversteurings, soos lae kaliumvlakke in die bloed.

Ernstige velreaksies geassosieer met flukonasoolbehandeling is aangemeld, insluitend geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS). Staak die gebruik van FLUCONAZOLE FRESENIUS en kry dadelik mediese hulp as jy enige van die simptome opmerk wat verband hou met hierdie ernstige velreaksies, beskryf in afdeling 4.

Ander medisyne en FLUCONAZOLE FRESENIUS

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

Die effek van die behandeling kan beïnvloed word as FLUCONAZOLE FRESENIUS gelyktydig met sekere ander medisyne gebruik word. Lig asseblief jou dokter of ander gesondheidsorgverskaffer in as jy enige van die volgende medisyne neem of gebruik:

- **Abrositinib** (gebruik vir die behandeling van atopiese dermatitis, ook bekend as atopiese ekseem).
- **Alfentaniel** ('n sterk pynstiller).
- **Amiodaroon** (vir onreëlmatige hartklop).
- **Amitriptilien, nortriptilien** (gebruik vir die behandeling van depressie).

- **Amfoterisien B** (gebruik vir die behandeling van swaminfeksies).
- **Astemisool** ('n antihistamien vir allergieë) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie"**).
- **Bensodiasepiene** soos midasolaam of triasolaam (sekere slaappille).
- **Kalsiumkanaalblokkeerders** soos nifedipien, isradipien, verapamiel, nikardipien, amlodipien, felodipien (gebruik by die behandeling van hartritmeversteurings en hoë bloeddruk).
- **Karbaamasepien** (gebruik vir die behandeling van epilepsie).
- **Selekoksib** (gebruik vir die behandeling van inflammasie).
- **Siklosporien** (gebruik by orgaanoorplanting).
- **Sisapried** (gebruik vir die behandeling van sooibrand en om maagsuur te verlaag) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie"**).
- **Siklofosfamied** (word gebruik vir die behandeling van 'n hele aantal tipes kanker).
- **Didanosien** (gebruik by die behandeling van MIV/VIGS).
- **Eritromisien** ('n antibiotikum) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie**").
- **Everolimus** (gebruik vir die behandeling van verskeie soorte kanker en by orgaanoorplanting).
- **Fentaniel** (gebruik vir erge pyn).
- **Halofantrien** (gebruik vir die behandeling van malaria).
- **HMG-KoA-reduktaseremmers (sogenaamde statiene)** soos atorvastatien, simvastatien, fluvastatien (medisyne wat bloedlipiede verlaag).
- **Hidrochloortiasied** (gebruik om die vloei van urien te verhoog, 'n diuretikum).
- **Ibrutinib** (gebruik vir die behandeling van sekere soorte kanker).
- **Isoniasied** (gebruik vir die behandeling van tuberkulose ("TB")).
- **Ivakaftor** (alleen of in kombinasie met ander medisyne wat gebruik word by die behandeling van sistiese fibrose).

- **Losartaan** (gebruik vir die behandeling van hoë bloeddruk).
- **Lurasidoon** (gebruik vir die behandeling van skisofrenie).
- Medisyne wat algemeen gebruik word vir die behandeling van epilepsie.
- **Metadoon** ('n pynstiller, opioïed).
- **Midasolaam, triasolaam** (word gebruik om jou te help slaap of vir angs).
- **Nevirapien** (vir die behandeling van MIV/VIGS).
- **NSAIG's** (niesteroïdale anti-inflammatoriese middels), soos flurbiprofeen, ibuprofeen, naproksen, lornoksikaam, meloksikaam, diklofenak (gebruik vir die behandeling van pyn, inflammasie en koors).
- **Olaparib** (gebruik vir die behandeling van sekere soorte kanker).
- **Mondelike voorbehoedmiddels** ("die pil" – om swangerskap te voorkom).
- **Fenitoïen** (gebruik om epilepsie te beheer).
- **Pimosied** ('n sogenaamde neuroleptiese medisyne, gebruik vir die behandeling van geestessiektes) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie**").
- **Prednisoon** of ander steroïedbehandelings (kortisoonagtige medisyne wat by inflammasie en orgaanoorplantings gebruik word).
- **Kinidien** ('n medisyne wat gebruik word vir onreëlmatige hartklop) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie**").
- **Rifampisien of rifabutien** (gebruik vir die behandeling van tuberkulose en ander infeksies).
- **Sakinavir** (vir die behandeling van MIV/VIGS).
- **Sirolimus** (gebruik by orgaanoorplanting).
- **Sulfonielureums** soos chloorpropamied, glibenklamied, glipisied of tolbutamied (gebruik om diabetes te beheer).
- **Takrolimus** (gebruik by orgaanoorplanting).
- **Terfenadien** ('n antihistamien vir allergieë) (sien "**FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie"**).

- **Teofillien** (gebruik om asma te beheer) en medisyne verwant aan teofillien, genaamd die xantien-basisse.
- **Tofasitinib** (gebruik vir die behandeling van sekere tipes artritis en sere in die kolon).
- **Tolvaptaan** (word gebruik om die vloei van urien te verhoog, dit is 'n diuretikum).
- **Trimetreksaat** (gebruik vir die behandeling van pneumonie).
- **Vinka-alkaloïede** soos vinkristien en vinblastien (word gebruik vir die behandeling van sekere soorte kanker).
- **Vitamien A** (om aknee te behandel).
- **Vorikonasool** (gebruik vir die behandeling van swaminfeksies).
- **Warfarien** en ander medisyne van die kumarien- of indaandioon-tipe (bloedverdunningsmedisyne).
- **Sidovudien** (vir die behandeling van MIV/VIGS).

Swangerskap en borsvoeding

FLUCONAZOLE FRESENIUS moet nie aan jou gegee word as jy swanger is of jou baba borsvoed nie (sien "FLUCONAZOLE FRESENIUS moet nie aan jou gegee word nie").

Indien jy beplan om swanger te word, word dit aanbeveel dat jy een week wag na 'n enkele dosis flukonasool voordat jy swanger raak.
Vir langer kursusse van behandeling met flukonasool, praat met jou dokter oor die behoefte aan toepaslike kontrasepsie tydens behandeling wat vir een week na die laaste dosis moet voortduur.

FLUCONAZOLE FRESENIUS kan die risiko van 'n miskraam verhoog indien dit tydens die eerste of tweede trimester van swangerskap gegee word. Die gebruik van flukonasool in lae dosisse gedurende die eerste trimester kan die risiko dat 'n baba gebore word met geboortedefekte van die hart, bene en/of spiere effens verhoog.

Daar is berigte van babas wat gebore word met geboortedefekte aan die skedel, ore en die bene van die dye en elmboë by vroue wat vir drie maande of langer met hoë dosisse (400–800 mg per dag) flukonasool vir koksidiomikose behandel was. Die verband tussen flukonasool en hierdie gevalle is nie duidelik nie.

FLUCONAZOLE FRESENIUS is teenwoordig in borsmelk; jy moet nie FLUCONAZOLE FRESENIUS ontvang as jy jou baba borsvoed nie.

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 vir advies voordat FLUCONAZOLE FRESENIUS aan jou gegee word.

Bestuur en die gebruik van masjinerie

Jy moet dit in gedagte hou dat duiseligheid of aanvalle soms by mense wat FLUCONAZOLE FRESENIUS neem kan voorkom; wees dus versigtig wanneer jy bestuur of masjinerie gebruik (sien "**Moontlike newe-effekte**").

Dit is nie altyd moontlik om te voorspel tot watter mate FLUCONAZOLE FRESENIUS 'n pasiënt se daaglikse aktiwiteite kan beïnvloed nie. Pasiënte moet sorg dat hulle nie die bogenoemde aktiwiteite uitvoer nie totdat hulle weet hoe FLUCONAZOLE FRESENIUS hulle beïnvloed.

FLUCONAZOLE FRESENIUS bevat natrium

FLUCONAZOLE FRESENIUS bevat sout (natriumchloried).
Indien jy op 'n lae natrium (sout) dieet is, lig jou dokter of ander gesondheidsorgverskaffer daarvan in voordat hulle vir jou FLUCONAZOLE FRESENIUS gee.
FLUCONAZOLE FRESENIUS bevat tot 3,5 mg natrium (hoofkomponent van kook/tafelsout) in elke mL. Dit is gelykstaande aan 0,175 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

3. Hoe FLUCONAZOLE FRESENIUS aan jou gegee sal word

Daar word nie van jou verwag om FLUCONAZOLE FRESENIUS aan jouself toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseer is om dit te doen.

FLUCONAZOLE FRESENIUS sal deur middel van 'n drup (stadige inspuiting in 'n aar) aan jou toegedien word.

Die dosis sal deur jou dokter bepaal word.

Behandeling sal normaalweg aangaan totdat die infeksie opgeklaar het.

Pasiënte met nierprobleme

Jou dokter sal die dosis aanpas volgens jou nierfunksie.

Kinders

Jou dokter sal die dosis by kinders bepaal.

Indien jy meer FLUCONAZOLE FRESENIUS ontvang as wat jy moes:

Aangesien 'n gesondheidsorgverskaffer FLUCONAZOLE FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van 'n oordosering sal jou dokter egter die oordosering behandel.

Indien jy bekommerd is dat jy te veel ontvang het of enige vrae het oor die dosis, praat met jou dokter of ander gesondheidsorgverskaffer.

Indien 'n dosis van FLUCONAZOLE FRESENIUS oorgeslaan word

Aangesien 'n gesondheidsorgverskaffer FLUCONAZOLE FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

Indien jy dink dat jy oorgeslaan is met 'n dosis, praat asseblief met jou dokter of gesondheidsorgverskaffer.

Indien jy enige verdere vrae het, vra jou dokter of ander gesondheidsorgverskaffer.

4. Moontlike newe-effekte

FLUCONAZOLE FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir FLUCONAZOLE FRESENIUS aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy FLUCONAZOLE FRESENIUS ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om FLUCONAZOLE FRESENIUS te ontvang en lig jou dokter dadelik in:

- 'n Skielike allergiese reaksie met kortasem, uitslag, hyging en 'n daling in bloeddruk.
- Swelling van die gesig, lippe, tong en lugpyp met hyging en moeilike asemhaling.
- Erge, wydverspreide veluitslag met blase en afskilfering van die vel.
- Stuipe of epileptiese aanvalle (konvulsies).
- Lewerprobleme en toksisiteit wat lei tot abnormale swakheid, verlies aan eetlus, aanhoudende naarheid, braking en/of geelsug (vergeling van die vel, wit van die oë en binnekant van die mond).
- Afname in die aantal selle in die sirkulasie wat kan lei tot bloedarmoede, verhoogde vatbaarheid vir infeksie, maklike kneusing of bloeding.
- Infeksie met simptome van koors en 'n ernstige agteruitgang van jou algemene toestand, of koors met plaaslike infeksie, bv. seer keel, faringeale pyn (agterkant van die keel), mond- of urienwegprobleme.
- Veranderinge in die hartritme.

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

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

Gereelde newe-effekte:

- Hoofpyn.
- Veluitslag.
- Mislike gevoel (naarheid).
- Opbring (braking).
- Maagpyn of pyn.
- Diarree.
- Veranderinge in bloedtoetsresultate van lewerfunksie.

Minder gereelde newe-effekte:

- Veranderinge in die smaak van kos, droë mond.
- Duiseligheid.
- Swak spysvertering.
- Winderigheid (flatulensie).
- Verlies aan eetlus.
- Jeuking of uitslag, striemsels, swelling of blaasvorming (netelroos).
- Sweet meer.
- Verlies aan eetlus.
- Veranderinge in bloedtoetsresultate van die nierfunksie.
- Abnormale slaap (slaperigheid, lomerigheid).
- Gevoelloosheid, bewing.
- Pyn in spiere.
- Voel swak en moeg.
- Koors.
- Verhoogde bloedvlakke van vette (cholesterol en trigliseriede).
- Verlaagde kaliumvlakke, wat lei tot swakheid en 'n onreëlmatige of vinnige hartklop.
- Haarverlies (alopesie).

Newe-effekte met onbekende frekwensie:

- Ernstige velreaksies waaronder 'n geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS).

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

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, raadpleeg jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van FLUCONAZOLE FRESENIUS te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om FLUCONAZOLE FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 25 °C. Moenie vries nie. Bewaar die produk in die karton totdat dit benodig word vir gebruik.

Moenie FLUCONAZOLE FRESENIUS neem na die vervaldatum wat op die kartonhouer en die etiket aangedui word nie. Die vervaldatum dui op laaste dag van daardie maand.

Die produk moet onmiddellik nadat dit oopgemaak is gebruik word.

Gebruik slegs as die oplossing helder en sonder sigbare deeltjies is. Moenie gebruik as die bottel beskadig is nie.

Die bottels is slegs vir eenmalige gebruik. Sodra dit gebruik is, moet ontslae geraak word van die bottels en enige oorblywende inhoud.

Medisynes moet nie via afvalwater of huishoudelike afval weggedoen word nie. Vra jou apteker hoe om ontslae te raak van medisyne wat nie langer benodig word nie. Hierdie maatreëls sal help om die omgewing te bewaar.

6. Inhoud van die pakkie en ander inligting

Wat FLUCONAZOLE FRESENIUS bevat

Die aktiewe bestanddeel is flukonasool. 1 mL oplossing vir infusie bevat 2 mg flukonasool.

Een bottel met 50 mL FLUCONAZOLE FRESENIUS oplossing vir infusie bevat 100 mg flukonasool.

Een bottel met 100 mL FLUCONAZOLE FRESENIUS oplossing vir infusie bevat 200 mg flukonasool.

Een bottel met 200 mL FLUCONAZOLE FRESENIUS oplossing vir infusie bevat 400 mg flukonasool.

Die ander bestanddele is natriumchloried, water vir inspuiting, soutsuur of natriumhidroksied (vir aanpassing van die pH).

Suikervry.

Hoe FLUCONAZOLE FRESENIUS lyk en inhoud van die pakkie

'n Helder tot byna kleurlose steriele oplossing in helder, deursigtige bottelverpakking poliëtileen (KabiPac) bottels van 50 mL; 100 mL en 200 mL.

50 mL oplossing word gevul in 'n 100 mL helder, deursigtige poliëtileenbottelverpakking met dop en 'n broombutielrubberskyf met 'n hanger aan die onderkant.

100 mL oplossing word gevul in 'n 100 mL helder, deursigtige poliëtileenbottelverpakking met dop en 'n broombutielrubberskyf met 'n hanger aan die onderkant.

200 mL oplossing word gevul in 'n 250 mL helder, deursigtige poliëtileenbottelverpakking met dop en 'n broombutielrubberskyf met 'n hanger aan die onderkant.

Verpakkingsgroottes van 1, 10; 20; 25; 30; 40 of 60 bottels.

Nie alle houergroottes en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

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Registrasienommer

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Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.