

# BIO FLUCONAZOLE

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S4

BIO FLUCONAZOLE 50 mg tablets  
BIO FLUCONAZOLE 150 mg tablets  
BIO FLUCONAZOLE 200 mg tablets  
Fluconazole  
Sugar free

### Read all of this leaflet carefully before you start taking BIO FLUCONAZOLE.

- 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.
- BIO FLUCONAZOLE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### WHAT IS IN THIS LEAFLET

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

### 1. What BIO FLUCONAZOLE is and what it is used for

Fluconazole, the active ingredient in BIO FLUCONAZOLE belongs to a group of medicines called antifungals.

#### In Adults:

BIO FLUCONAZOLE is usually used to prevent and treat fungal infections caused by organisms called *Cryptococcus* (a fungal infection in the brain) and *Candida* which can cause meningitis, vaginal and penis infections, systemic infections, infections of the throat and oesophagus and infections of the skin e.g. ringworm, athlete's foot, jock itch and nail infections.  
BIO FLUCONAZOLE can also be used to prevent fungal infections in patients receiving cancer treatment.

#### In children:

BIO FLUCONAZOLE is usually used to prevent and treat fungal infections caused by organisms called *Cryptococcus* (a fungal infection in the brain) and *Candida* which can cause meningitis, systemic infections, infections of the throat and oesophagus. BIO FLUCONAZOLE can also be used to prevent fungal infections in patients receiving cancer treatment.

### 2. What you need to know before you take BIO FLUCONAZOLE

#### Do not take BIO FLUCONAZOLE:

- if you are hypersensitive (allergic) to fluconazole or any of the other ingredients of BIO FLUCONAZOLE (listed in section 6).
- if you are taking an antihistamine medicine for allergies called astemizole and terfenadine.
- if you are taking a medicine called cisapride to increase your bowel movements.
- if you are taking pimozide (used for treating mental illness)
- if you are taking quinidine (used for treating heart arrhythmia)
- if you are taking erythromycin (an antibiotic for treating infections)
- if you are pregnant or breastfeeding
- if you have a kidney problem.

#### Warnings and precautions

- if you suffer from kidney problems.
- if you suffer from liver problems.
- if you develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain)
- if you suffer from heart disease, including heart rhythm problems
- if you have abnormal levels of potassium, calcium or magnesium in your blood.
- if you are using halofantrine
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking BIO FLUCONAZOLE. Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with BIO FLUCONAZOLE treatment
- if you are HIV positive.

#### Other medicines and BIO FLUCONAZOLE

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

#### Do not use the following medicine if you are taking BIO FLUCONAZOLE

- Cisapride a medicine used to increase bowel movements;
- Terfenadine and astemizole (an antihistamine for treating allergies)
- Pimozide (used for treating mental illness)
- Quinidine (used for treating heart arrhythmia)
- Erythromycin (an antibiotic for treating infections)

#### BIO FLUCONAZOLE may interact with the following medicines. Make sure your doctor knows if you are taking any of the following medicines:

- Halofantrine (used for treating malaria)
- Amiodarone (used for treating uneven heartbeats 'arrhythmias')
- Rifampicin or rifabutin (Anti-TB medicine)
- The diuretic (medicine that increases urination), hydrochlorothiazide
- Alfentanil, fentanyl (used as anaesthetic)
- Amitriptyline, nortriptyline (used as anti-depressant)
- Amphoterin B, voriconazole (anti-fungal)
- Blood thinning agents e.g. warfarin, indanedione or similar medicines
- Anti-anxiety medicines called benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- Medicines against epilepsy e.g. phenytoin, carbamazepine;
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension- high blood pressure)
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- Cyclosporinamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- Statins (atorvastatin, simvastatin and fluvastatin) used for reducing high cholesterol levels
- Olaparib (used for treating ovarian cancer)
- Cyclosporine, everolimus, sirolimus and tacrolimus, immunosuppressants used after organ transplants;
- Methadone (used for pain)
- Prednisone
- Antiretroviral medicines e.g. zidovudine and saquinavir (used in HIV infected patients)
- Oral antidiabetic medicines such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (a medicine for asthma)
- Tofacitinib (used for treating rheumatoid arthritis)
- Vitamin A (nutritional supplement)
- Oral contraceptives
- Ivacaftor (used for treating cystic fibrosis)

#### BIO FLUCONAZOLE with food, drink and alcohol

You can take BIO FLUCONAZOLE with or without a meal

#### Pregnancy, breastfeeding and fertility

You should not use BIO FLUCONAZOLE while you are pregnant or if you are breastfeeding.  
BIO FLUCONAZOLE taken during the first trimester of pregnancy may increase the risk of miscarriage.  
BIO FLUCONAZOLE taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.  
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 BIO FLUCONAZOLE.

#### Driving and using machines

If you suffer from dizziness, headaches, tiredness or nausea make sure that you are well enough to drive or operate machinery, as your ability to react may be impaired. It is not always possible to predict to what extent BIO FLUCONAZOLE may interfere with the daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BIO FLUCONAZOLE affects you.

### 3. How to take BIO FLUCONAZOLE

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

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

The tablets should be swallowed whole with a glass of water and should be taken the same time each day. Generally, the initial dose is 400 mg followed by 100 mg – 200 mg daily. The duration of treatment is usually 7 to 14 days but can be up to 3 – 12 months for fungus infections of the fingernails and toenails.

If you suffer from kidney problems or are an elderly person, your doctor will determine the most suitable dose for you based on your bodyweight.

Your doctor will tell you how long your treatment with BIO FLUCONAZOLE will last. Do not stop treatment early. If you have the impression that the effect of BIO FLUCONAZOLE is too strong or too weak, talk to your doctor or pharmacist.

**If you take more BIO FLUCONAZOLE than you should**  
General symptoms of overdosage are vomiting, irritability, sleeplessness, diarrhoea, stomach pain and cramps, loss of appetite for food, bulging fontanel, high levels of alkaline phosphates and gamma glutamyl transpeptidases, high calcium levels in blood, kidney failure, tiredness, joint pain skin redness, hives and rash, pins and needles of the tongue, depressed, hallucination and paranoid behaviour. See possible side effects for further possible symptoms. In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### If you forget to take BIO FLUCONAZOLE

Do not take a double dose to make up for forgotten individual doses.

### 4. Possible side effects

BIO FLUCONAZOLE can cause side effects. Not all side effects reported for BIO FLUCONAZOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO FLUCONAZOLE, please consult your health care provider for advice.

### If any of the following happen, stop taking BIO FLUCONAZOLE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity and anaphylaxis
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- skin rash or itching,
- fever and chills
- fainting
- flushing

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

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

- low levels of blood platelet (thrombocytopenia)
- low levels of white blood cells (granulocytes, neutrophils) in your blood that help defend against infections (agranulocytosis, leukopenia, neutropenia)
- low levels of red blood cells which can make skin pale and cause weakness or breathlessness (anaemia)
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver toxicity, inflammation, damage, and failure with the following symptoms: Dark or amber urine; loss of appetite; pale stools; stomach pain; unusual tiredness or weakness; yellow eyes or skin, high blood levels of alkaline phosphatase, alanine aminotransferase (ALT) and aspartate aminotransferase (AST)
- severe inflammation of the entire skin surface, including Stevens-Johnson syndrome (fever, skin blisters, skin peeling, painful skin, red eyes) and toxic epidermal necrolysis (blistering and peeling of the skin)
- Drug rash with eosinophilia and systemic symptoms (DRESS) syndrome is a severe adverse drug reaction characterized by an extensive skin rash, fever, facial swelling, enlarged lymph nodes and kidney or liver injury

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

### Tell your doctor of you notice any of the following:

#### Frequent side effects:

- headache
- abdominal pain
- diarrhoea
- loss of appetite
- nausea
- vomiting
- rash

#### Less frequent side effects:

- high cholesterol in the blood (hypercholesterolaemia)
  - high triglyceride in the blood (hypertriglyceridemia)
  - low levels of potassium in the blood resulting in convulsions, decreased urine, dry mouth and irregular heartbeat. (hypokalaemia)
  - decrease in appetite
  - sleepiness
  - sleeplessness
  - dizziness
  - seizures
  - nervousness
  - sudden feeling of cold with shivering accompanied by a rise in temperature, often with copious sweating (rigors)
  - muscle spasm (hyperkinesia)
  - pins and needles (paraesthesia)
  - changes in sense of taste
  - shaking (tremor)
  - loss of balance (vertigo)
  - abnormal vision
  - difficult digestion
  - thirst
  - wind
  - constipation
  - dry mouth
  - a rash of round, red welts on the skin that itch intensely, sometimes with dangerous swelling, caused by an allergic reaction (urticaria)
  - dry skin
  - abnormal smell
  - hair loss (alopecia)
  - adverse skin reaction to a drug
  - severe itching of the skin (pruritus)
  - increased sweating
  - a severe, usually drug-related reaction, characterized by an acute onset of mainly small non-follicular pustules on an erythematous base and spontaneous resolution usually within two weeks (acute generalised exanthematous pustulosis)
  - severe inflammation of the entire skin surface (dermatitis exfoliative)
  - rapid swelling, of the area beneath the skin or mucosa (angioedema)
  - build up of fluid in the tissues of the face (face oedema)
  - high level of muscle tone or tension (hypertonia)
  - muscle pain (myalgia)
  - large volumes of dilute urine
  - female sexual dysfunction
  - abnormal vaginal bleeding between periods (intermenstrual bleeding)
  - abnormally heavy bleeding at menstruation (menorrhagia)
  - flow of a whitish, yellowish, or greenish discharge from the vagina of the female that may be normal or that may be a sign of infection (leucorrhoea)
  - tiredness
  - general feeling of being unwell (malaise)
  - lack of energy (asthenia)
  - fever
- 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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIO FLUCONAZOLE.

### 5. How to store BIO FLUCONAZOLE

Store all medicines out of reach of children.  
Store at or below 25 °C in a dry place. Keep the container well closed.

Do not use BIO FLUCONAZOLE after the expiry date stated on the blister strip, label or carton.  
Return all unused medicine to your pharmacist.  
Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### 6. Contents of the pack and other information

#### What BIO FLUCONAZOLE contains

The active substance is fluconazole. Each tablet contains 50 mg, 150 mg or 200 mg fluconazole respectively. The other ingredients are microcrystalline cellulose, dibasic calcium phosphate (anhydrous), croscarmellose sodium, povidone, magnesium stearate and purified water.

#### What BIO FLUCONAZOLE looks like and contents of the pack

BIO FLUCONAZOLE 50 mg tablets: White to off-white, circular, flat, bevelled edged, uncoated tablets with "NJB" engraved on one face and "50" on the other, free from cracks, mottling and chips in the tablet surface.  
BIO FLUCONAZOLE 150 mg tablets: White to off-white, capsule shaped, biconvex uncoated tablets with "NJB" engraved on one face and "150" on the other, free from cracks, mottling and chips in the tablet surface.  
BIO FLUCONAZOLE 200 mg tablets: White to off-white, circular, flat, bevelled edged, uncoated tablets with "NJB" engraved on one face and "200" on the other, free from cracks, mottling and chips in the tablet surface.  
BIO FLUCONAZOLE tablets are packed in a white HDPE container with a white PP closure and rayon coil, each containing 14, 30, 100 or 500 tablets. Each container is sealed with a tamper evident foil inner seal.  
BIO FLUCONAZOLE 150 mg are available in transparent PVC/Aclar blister packs of 1 or 4 tablets. Each blister strip contains 1 or 4 tablets in a blister and are packed in an outer carton.

#### Holder of Certificate of Registration

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BIO FLUCONAZOLE 150 mg: 42/20.2.2/0684  
BIO FLUCONAZOLE 200 mg: 42/20.2.2/0690

PIL 420566/684/690-1

# BIO FLUCONAZOLE

## PASIENT INLIGTINGSBLAD

### SKEDULERING STATUS:

54

BIO FLUCONAZOLE 50 mg tablette  
BIO FLUCONAZOLE 150 mg tablette  
BIO FLUCONAZOLE 200 mg tablette  
Flukonasool  
Suikervry

### Lees hierdie inligtingsblad sorgvuldig voordat u begin om BIO FLUCONAZOLE te neem

- Bêre hierdie voubljiet. Dit mag nodig wees dat u dit weer lees.
- Indien u enige verdere vrae het, raadpleeg u dokter, apteker, verpleegster of enige ander gesondheidsorgver skaffer.
- BIO FLUCONAZOLE is vir u persoonlik voorgeskryf en u moet nie hierdie medikasie met enige ander persone deel nie. Dit kan skadelik vir hul wees, selfs al is hul simptome dieselfde as wat u ervaar.

### WAT HIERDIE INLIGTINGSBLAD BEVAT

1. Wat BIO FLUCONAZOLE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u BIO FLUCONAZOLE drink
3. Hoe om BIO FLUCONAZOLE te drink
4. Moontlik nuwe-effekte
5. Hoe om BIO FLUCONAZOLE te bêre
6. Inhoud van die pak en ander inligting

### 1. Wat BIO FLUCONAZOLE is en waarvoor dit gebruik word

Flukonasool, die aktiewe bestanddeel in BIO FLUCONAZOLE, behoort aan 'n groep medisyne genaamd antifungale of swamdodende middels.

### In Volwassenes:

BIO FLUCONAZOLE word gewoonlik gebruik om swaminfeksies, wat veroorsaak word deur organismes genoem Cryptococcus ('n swaminfeksie in die brein) en Candida, wat meningitis kan veroorsaak, vaginale en penis infeksies, sistemiese infeksies, infeksies van die keel en oesofagus en infeksies van die vel, bv. ringwurm, atletvoet, onderbroekjeuk en nael infeksies, te voorkom en te behandel. BIO FLUCONAZOLE kan ook gebruik word om swaminfeksies te voorkom in pasiënte wat kankerbehandeling ontvang.

### In kinders:

BIO FLUCONAZOLE word gewoonlik gebruik om swaminfeksies, wat veroorsaak word deur organismes genoem Cryptococcus ('n swaminfeksie in die brein) en Candida, wat meningitis kan veroorsaak, sistemiese infeksies, infeksies van die keel en oesophagus, te voorkom en te behandel. BIO FLUCONAZOLE kan ook gebruik word om swaminfeksies te voorkom in pasiënte wat kankerbehandeling ontvang.

### 2. Wat u moet weet voordat u BIO FLUCONAZOLE drink Moenie BIO FLUCONAZOLE drink:

- as u hipersensitief (allergies) is vir flukonasool of enige van die ander bestanddele van BIO FLUCONAZOLE (in afdeling 6 genoem).
- as u 'n antihistamienmedikasie neem vir allergieë wat astemizool of tenfenadien genoem word.
- as u 'n medisyne genaamd sisapried gebruik om u stoelgang te verhoog
- as u pimozeid gebruik (gebruik vir die behandeling van geestesongesteldheid)
- as u kinidien gebruik (gebruik vir die behandeling van hartaritmieë)
- as u eritromisien gebruik ('n antibiotika vir die behandeling van infeksies)
- as u swanger is of borsvoed
- as u 'n nierprobleem het.

### Waarskuwings en voorsorgmaatreëls

- as u aan nierprobleme ly.
- as u aan leverprobleme ly.
- as u tekens van 'adrenale ontoereikendheid' ontwikkel waar die biniere nie voldoende hoeveelhede sekere steroïedhormone produseer nie, soos kortisol (chroniese of langdurige moegheid, spierswakheid, verlies van eetlus, gewigsverlies, buikpyn)
- as u aan hartsiektes ly, insluitend hartritmeprobleme
- as u abnormale kalium-, kalsium- of magnesiumvlakke in u bloed het.
- as u halofantrien gebruik
- as u ooit erge veluitslag of velafskilfering, blase en/of mondseer opgedoen het nadat u BIO FLUCONAZOLE geneem het. Ernstige velreaksies, insluitend genesmid delreaksie met eosinofilie en sistemiese simptome (DRESS) is aangemeld, wat verbind is met BIO FLUCONAZOLE – behandeling
- as u MIV -positief is

### Ander medisyne en BIO FLUCONAZOLE

- Lig altyd u gesondheidsorgverskaffer in as u ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

### Moenie die volgende medisyne gebruik as u BIO FLUCONAZOLE neem nie

- Cisapride 'n medisyne wat gebruik word om die stoelgang te verhoog;
- Terfenadien en astemizool ('n antihistamien vir die behandeling van allergieë)
- Pimozeid (gebruik vir die behandeling van geestesongesteldheid)
- Kinidien (vir die behandeling van hartaritmieë)
- Eritromisien ('n antibiotika vir die behandeling van infeksies)

### BIO FLUCONAZOLE kan interaksie hê met die volgende medisyne. Maak seker dat u dokter weet as u een van die volgende medisyne gebruik:

- Halofantrien (gebruik vir die behandeling van malaria)
- Amiodaroon (gebruik vir die behandeling van ongelukke hartklop/ aritmieë)
- Rifampisien of rifabutien (medisyne teen TB)
- Die diuretikum (medisyne wat urinering verhoog), hidrochloordiasied
- Alfentanil, fentanil (gebruik vir narkose)
- Amitriptilien, nortriptilien (gebruik as anti-depressant)
- Amfetoriesien B, vorikonasool (swamdodend)
- Bloedverdunner, bv. warfariën, indanedione of soortgelyke medisyne
- Anti-angskmedisyne genaamd bensodiazepiene (midazolam, triazolam of soortgelyke medisyne) wat u help slaap of help met angst
- Medisyne teen epilepsie bv. fenitoïen, karbamasepin;
- Nifedipien, isradipien, amlodipien, verapamil, felodipien en losartan (vir hipertensie- hoë bloeddruk)
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diklofenak (nie-steroidale anti-inflammatoriese middels (NSAID))
- Siklofosfamied, vinka -alkaloïede (vinkristien, vinblastien of soortgelyke medisyne) wat gebruik word vir die behandeling van kanker
- Statiene (atorvastatin, simvastatin en fluvastatin) wat gebruik word om hoë cholesterolvlakke te verlaag
- Olarapib (gebruik vir die behandeling van eierstokkanker)
- siklosporien, everolimus, sirolimus en takrolimus, immuunonderdrukkers wat gebruik word na orgaanplantings;
- Metadon (gebruik vir pyn)
- Prednison
- Antiretrovirale medisyne bv. zidovudine en saquinavir (gebruik by MIV- pasiënte)
- Mondelinge antidiabetiese middels soos chloorpropamied, glibenklamied, glipisied of tolbutamied.
- Teofilien (medisyne vir asma)
- Tofastimib (gebruik vir die behandeling van rumatoïede artritis)
- Vitamien A (voedingsaanvulling)
- Mondelinge voorbehoedmiddels
- Ivakaftor (gebruik vir die behandeling van sistiese fibrose)

### BIO FLUCONAZOLE wat voedsel en alkohol

U kan BIO FLUCONAZOLE neem met of sonder 'n maaltyd

### Swangerskap, borsvoeding en fertiliteit

U moet nie BIO FLUCONAZOLE gebruik terwyl u swanger is of as u borsvoed nie.

Die risiko van miskraam kan verhoog word, as BIO FLUCONAZOLE tydens die eerste trimester van swangerskap geneem word.

Die neem van BIO FLUCONAZOLE in lae dosisse in die eerste trimester, kan die risiko dat 'n baba gebore word met geboortedefekte wat die bene en/of spiere beïnvloed, effens verhoog.

As u swanger is of borsvoed, dink u is swanger of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u BIO FLUCONAZOLE neem.

### Bestuur en gebruik van masjinerie

As u duiseligheid, hoofpyn, moegheid of naarheid het, moet u seker maak dat u goed genoeg voel om te bestuur of masjinerie te gebruik, aangesien u reaksievermoë benadeel kan word.

Dit is nie altyd moontlik om te voorspel in watter mate BIO FLUCONAZOLE u daaglikse aktiwiteite kan beïnvloed nie. U moet seker maak dat u nie aan die bogenoemde aktiwiteite deelneem voordat u bewys is tot watter mate BIO FLUCONAZOLE u beïnvloed nie.

### 3. Hoe om BIO FLUCONAZOLE te neem

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Gebruik altyd BIO FLUCONAZOLE presies soos u dokter of apteker u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Die tablette moet heel met 'n glas water ingesluk word en elke dag op dieselfde tyd geneem word.

Oor die algemeen is die aanvanklike dosis 400 mg, gevolg deur 100 mg - 200 mg daaglik. Die duur van die behandeling is gewoonlik 7 tot 14 dae, maar kan vir swam infeksies van die naels en toonnaels tussen 3 - 12 maande duur.

As u aan nierprobleme ly of 'n bejaarde is, sal u dokter die gepaste dosis vir u bepaal op grond van u liggaamsgewig. Jou dokter sal jou vertel hoe lank jou behandeling met BIO FLUCONAZOLE sal duur. Moenie die behandeling vroeg stop nie. Vertel u dokter of apteker as u die indruk het dat die effek van BIO FLUCONAZOLE te sterk of te swak is.

### As u meer BIO FLUCONAZOLE neem as wat u moet

Algemene simptome van oordosering is braking, prikkelbaarheid, slapeloosheid, diarree, maagpyn en krampe, verlies aan eetlus, bultende fontanel, hoë vlakke alkaliese fosfate en gammaglutamiel -transpeptidases, hoë kalsiumvlakke in die bloed, nierversaking, moegheid, gewrigspyn velrooiheid, bulle en uitslag, spelde en naalde van die tong, depressie, hallusinasie en paranoiae gedrag. Sien moontlike nuwe -effekte vir verdere moontlike simptome.

In die geval van 'n oordosis, kontak u dokter of apteker. As daar nie 'n beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

### AS u vergeet om BIO FLUCONAZOLE te drink

Moenie 'n dubbele dosis gebruik om vir vergeete individuele dosisse op te maak nie.

### 4. Moontlike nuwe-effekte

BIO FLUCONAZOLE kan nuwe -effekte veroorsaak. Nie alle nuwe -effekte wat al aangemeld is vir BIO FLUCONAZOLE is ingesluit in hierdie inligtingsblad nie.

Indien u algemene gesondheid versleg of as u enige ongunstige effekte ervaar, raadpleeg met u gesondheidsorgverskaffer vir advies.

### As een van die volgende gebeur, staak die gebruik van BIO FLUCONAZOLE en lig onmiddellik u dokter in, of gaan na die ongevallen afdeling in u naaste hospitaal:

- Hipersensitiwiteit en anafaksie
- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat asemhaling of sluk bemoeilik.
  - uitslag of jeuking;
  - koors en of kouekoors
  - floute
  - gloede

Hierdie is almal ernstige nuwe-effekte. Indien u dit ervaar, mag u 'moontlik' 'n ernstige reaksie teenoor BIO FLUCONAZOLE hê. U mag dringende mediese aandag of hospitalisasie benodig.

### Lig u dokter onmiddellik in of gaan na die naaste noodgevallen afdeling van u naaste hospitaal indien u enige van die volgende waarneem:

- lae bloedplaatjie vlakke (trombositopenie)
- lae kaliumvlakke in die bloed (granulosietie, neutrofile) in u bloed wat u help beskerm teen infeksies (agranulositose, leukopenie, neutropenie)
- lae vlakke van rooibloedselle wat die vel bleek kan maak en swakheid of asemloosheid kan veroorsaak (bloedarmoede)
- abnormale elektrokardiogram (EKG), verandering in hartklop of ritme
- lewertoeksiteit, ontsteking, skade en falings met die volgende simptome: Donker of amber urine; eetlus verlies; bleek stoelgange; maagpyn; ongewone moegheid of swakheid; geel oë of vel, hoë bloedvlakke van alkaliese fosfatase, alanien aminotransferase (ALT) en aspartaat aminotransferase (AST)
- ernstige ontsteking van die hele veloppervlak, insluitend Stevens-Johnson-sindroom (koors, velblase, velafskilfering, pynlike vel, rooi oë) en toksiese epidermale nekrolise (blase en afskilfering van die vel)
- Geneesmiddeluitslag met eosinofilie en sistemiese simptome (DRESS) sindroom is 'n ernstige nadelige geneesmiddelreaksie wat gekenmerk word deur uitgebreide veluitslag, koors, swelling van die gesig, vergroete limfnodes en nier- of lewerskade

Dit is alles ernstige nuwe -effekte. U mag dringende mediese aandag benodig.

### Lig u dokter is as u enige van die volgende opmerk:

*Algemene nuwe-effekte:*

- hoofpyn
- maagpyn
- diarree
- verlies van eetlus
- naarheid
- braking
- uitslag

*Minder algemene nuwe-effekte:*

- hoë cholesterol in die bloed (hipercholesterolemie)
- hoë trigliseriede in die bloed (hipertrigliceridemie)
- lae kaliumvlakke in die bloed wat konvulsies, verminderde urine, droë mond en onreëlmatige hartklop tot gevolg het. (hipokalemie)
- afname in eetlus
- slapeloosheid
- duiseligheid
- aanvalle
- sensuïgtigheid
- skielike koue gevoel met bewing gepaard met 'n styging in temperatuur, dikwels met baie sweet (rigor)
- spierspasma (hiperkinesie)
- naalde en spelde (parastesie)
- verandering in smaak
- bewegierheid (tremor)
- verlies van balans (vertigo)
- abnormale visie
- moeilike spysvertering
- dorstigheid
- winderigheid
- hardlywigheid
- droë mond
- 'n uitslag van ronde, rooi kolle op die vel wat intens jeuk, soms met gevaarlike swelling, veroorsaak deur 'n allergiese reaksie (urtikaria)
- droë vel
- abnormale reuk
- haarverlies (alopecia)
- nadelige velreaksie teenoor die geneesmiddel
- erge jeuk van die vel (pruritus)
- verhoogde sweet
- 'n ernstige, gewoonlik geneesmiddelverwante reaksie, gekenmerk deur 'n akute aanvang van hoofsaaklik klein nie-follikulêre pustules op 'n eritematiese basis en spontane oplossing gewoonlik binne twee weke (akute veralgemeende eksantemiese pustulose)
- ernstige ontsteking van die hele veloppervlak (eksfoliatiewe dermatitis)
- vinnige swelling van die area onder die vel of slymvlies (angio -oedeem)
- ophoping van vloeistof in die weefsels van die gesig (oedeem van die gesig)
- hoë spiertonus of spanning (hipertonie)
- spierpyn (myalgie)
- groot hoeveelhede verdunde urine
- vroulike seksuele disfunksie
- abnormale vaginale bloeding tussen menstruasies (intermenstruele bloeding)
- abnormale swaar bloeding tydens menstruasie (menorragie)
- vloei van 'n witterige, geel of groenagtige afskeiding uit die vagina van vroue wat normaal kan wees of wat 'n teken van infeksie kan wees (leucorrhoea)
- moegheid
- algemene gevoel van ongesteldheid (malaise)
- gebrek aan energie (astenie)
- koors

As u enige nuwe -effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

### Aanmelding van nuwe-effekte

Praat met u dokter, apteker of verpleegkundige as u nuwe-effekte kry. U kan ook nuwe -effekte by SAHPRA aanmeld via 'die "6.04 verslagdoening oor ongewenste geneesmiddelreaksies", aanlyn gevind onder die publikasies van SAHPRA: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BIO FLUCONAZOLE te verskaf.

### 5. Hoe om BIO FLUCONAZOLE te bêre

Bewaar alle medisyne buite die bereik van kinders. Bewaar teen of benede 25 °C in 'n droë plek. Hou die houerdig toe.

Moenie BIO FLUCONAZOLE gebruik na die vervaldatum op die stulpstroom, etiket of karton nie. Oorhandig alle ongebruikte medisyne aan u apteker. Moenie ongebruikte medisyne in dreine en rioolstelsels weggooi nie (bv. toilette).

### 6. Inhoud van die pak en ander inligting

#### Wat BIO FLUCONAZOLE bevat

Die aktiewe bestanddeel is flukonasool. Elke tablet bevat onderskeidelik 50 mg, 150 mg of 200 mg flukonasool. Die ander bestanddele is mikrokristallyne sellulose, dibasiese kalsiumfosfaat (watervry), natrium krosmarmellose, povidoon, magnesiumstearaat en gesuiwerde water.

#### Hoe BIO FLUCONAZOLE lyk en ander inhoud van die pak

BIO FLUCONAZOLE 50 mg tablette: Wit tot naaswit, sirkelvormig, plat, afgeronde, onbedekte tablette met "NJB" gegraaver aan die een kant en "50" aan die ander kant, vry van krake, vlekke en merke op die tabletoppervlak. BIO FLUCONAZOLE 150 mg tablette: Wit tot naaswit, kapselvormige, bikonvekse, onbedekte tablette met "NJB" gegraaver op die een kant en "150" aan die ander kant, vry van krake, vlekke en merke op die tabletoppervlak. BIO FLUCONAZOLE 200 mg tablette: Wit tot naaswit, sirkelvormig, plat, afgeronde, onbedekte tablette met "NJB" gegraaver op die een kant en "200" aan die ander kant, vry van krake, vlekke en merke op die tabletoppervlak. BIO FLUCONAZOLE 50 en 200 mg tablette word verpak in 'n wit HDPE houer met 'n wit PP sluiting en rayon spoel, elk met 14, 30, 100 of 500 tablette. Elke houer word versêl met 'n klepverf -binneste seël. BIO FLUCONAZOLE 150 mg is beskikbaar in deursigtige PVC/Aclar blisterverpakings van 1 of 4 tablette. Elke stulpstroom bevat 1 of 4 tablette in 'n strook en word in 'n buitenste karton verpak.

#### Houer van die Registrasie Sertifikaat

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#### Datum van laaste hersiening

09 September 2021

#### Registrasie nommer

BIO FLUCONAZOLE 50 mg: 42/20.2.2/0566  
BIO FLUCONAZOLE 150 mg: 42/20.2.2/0694  
BIO FLUCONAZOLE 200 mg: 42/20.2.2/0680

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