

# STALENE 200 (CAPSULES)

Fluconazole 200 mg

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## What STALENE 200 is used for

STALENE 200 is used to treat infections caused by fungi and may also be used to stop you from getting a candidal infection. The most common cause of fungal infections is yeast called *Candida*.

Fluconazole are used to treat the following type of fungal infections:

- Cryptococcal meningitis (fungal infection in the brain)
- Infections caused by *Candida* and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush (infection affecting the lining of the mouth, throat and denture sore mouth)
- Genital thrush (infection of the vagina or penis)
- Skin infections (e.g. athlete's foot, ringworm, jock itch, nail infection)

STALENE 200 is also used to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- reduce recurrence of vaginal thrush
- stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)

## How STALENE 200 works

Fluconazole is a triazole antifungal agent that kills yeast and fungi.

## Before you use STALENE 200

### -When you must not use it

- ⊗ If you are allergic (hypersensitive) to Fluconazole or to other antifungal drugs.
- ⊗ If you are allergic (hypersensitive) to any of the other ingredients of STALENE 200.
- ⊗ If you are taking Terfenadine (antihistamine drug for allergies)
- ⊗ If you are taking Cisapride (used for stomach upsets)
- ⊗ If you are Pregnant and breast-feeding
  - ⇒ STALENE 200 should be avoided except in patients with severe or potentially life-threatening fungal

infections in whom Fluconazole may be used if the anticipated benefit outweighs the possible risk to the fetus.

- ⇒ Fluconazole is found in human breast milk at concentrations similar to blood levels, hence its use in nursing mothers is not recommended.

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking STALENE 200.

### -Before you start to use it

Inform your doctor if you have such conditions:

- Liver or kidney problems
- Severe skin reaction develops
- AIDS
- Invasive/ systemic fungal infections
- Pregnant or planning to become pregnant
- Breast feeding
- Had symptoms of anaphylaxis (severe allergic reactions) with other "azole" drugs in the past.

In such cases, please consult your doctor before taking the medicine.

### -Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines. This is because STALENE 200 can affect the way some medicines work.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Blood thinning drugs (Anticoagulants) e.g. Warfarin
- Drugs for anxiety (Short-Acting Benzodiazepines) e.g. Midazolam
- Cisapride
- Cyclosporin
- Hydrochlorothiazide
- Oral contraceptives
- Phenytoin
- Rifabutin
- Rifampicin
- Antidiabetic drugs e.g. Chlorpropamide, Glibenclamide, Glipizide and Tolbutamide
- Tacrolimus
- Terfenadine
- Theophylline
- Zidovudine
- Astemizole

## How to use STALENE 200

### -How much to use

Oral

Adults:

*Cryptococcal Meningitis and Cryptococcal Infections at Other Sites:*

Usual Dose: 400 mg on the first day followed by 200-400 mg once daily. Duration of treatment is usually at least 6-8 weeks for cryptococcal meningitis.

*Prevention of Relapse of Cryptococcal Meningitis in Patients with AIDS:*

After receiving a full course of primary therapy, Fluconazole may be administered at a daily dose of 200 mg until the doctor tells you to stop.

*Invasive Candidal Infections:*

Usual Dose: 400 mg on the 1st day followed by 200 mg daily.

*Candidal Infections of the Mouth or Throat*

Usual Dose: 50 mg once daily for 7-14 days.

*Candidal Infections of the Mouth (Associated with Dentures):*

Usual Dose: 50 mg once daily for 14 days.

*Vaginal Thrush or Balanitis (inflammation of the head of the penis):*

150 mg administered as a single oral dose.

*To Prevent Candidal Infections:*

Recommended Dosage: 50-400 mg once daily, based on the patient's risk for developing fungal infection.

*Dermal Infections (including athlete's foot, ringworm infection and candida infections):*

Recommended Dosage: 150 mg once weekly or 50 mg once daily. Duration of treatment is normally 2-4 weeks but athlete's foot may require treatment for up to 6 weeks.

*Tinea Versicolor (fungal infection of the skin):*

Recommended Dose: 50 mg once daily for 2-4 weeks.

Children: For those with similar infections in adults, the duration of treatment is determined by the doctor. The maximum adult daily dosage should not be exceeded in children. Fluconazole is taken as a single dose each day.

*Candida Infections of the Mucous Linings:*

Recommended Dosage: 3 mg per kg daily.

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*Systemic Candidal Infection (spreads throughout the body) and Cryptococcal (a type of fungus) Infections:*

Recommended Dosage: 6-12 mg/kg daily, depending on the severity of the disease.

For children with impaired renal function, see dosing in *If you have kidney problems*.

A maximum dosage of 400 mg daily should not be exceeded in children.

The use of STALENE 200 for genital candidiasis in children < 16 years is not recommended unless antifungal treatment is necessary and no suitable alternative agent is available.

Children < 4 weeks: In the first 2 weeks of life, the same dosing as in older children should be used but to be taken every 72 hrs. During weeks 3 and 4 of life, the same dose should be used every 48 hrs.

A maximum dosage of 12 mg/kg every 72 hrs should not be exceeded in children in the first 2 weeks of life. For children between 3 and 4 weeks of life, 12 mg/kg every 48 hrs should not be exceeded.

#### *Elderly:*

The usual adult dose should be used unless you have kidney problems.

#### *If you have kidney problems:*

Your doctor may modify your dose depending on your kidney function.

#### *Instructions for Use/Handling:*

Capsules should be swallowed whole.

#### *-When to use it*

You may take STALENE 200 on an empty stomach or with meals.

It is best to take your capsule at the same time of each day.

#### *-How long to use it*

Your doctor will tell you how long you should continue to take this medicine.

#### *-If you forget to use it*

If you miss a dose, take the next dose as soon as you remember, provided that you do not take more than the recommended dose in 24 hours. If it is almost time for your next dose, do not take the dose that you missed.

Do not take a double dose.

#### *-If you use too much (Overdose)*

Taking too many capsules at once may make you unwell. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behavior).

In case you accidentally take too much and experienced the above mentioned overdose symptoms, contact your doctor immediately or contact your nearest hospital.

#### **While you are using it**

##### -Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking STALENE 200.

Tell your doctor immediately if you become pregnant while taking this medication.

##### -Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give STALENE 200 to anyone else, even if they have the same symptoms or condition as you.

##### -Things to be careful of

Activities requiring mental alertness:

Do not drive a car or operate potentially dangerous tools or machines.

#### **Side effects**

Fluconazole is generally well tolerated.

But like with all medicines, STALENE 200 is likely to have undesirable effects, although not everybody gets them.

*The most common undesirable effects associated with fluconazole are:*

- Headache
- Rash
- Abdominal pain, diarrhea, flatulence (the release of excessive gas in the stomach and intestine), nausea
- Changes in liver and kidney function test results and liver abnormalities in patients with underlying diseases e.g. AIDS and cancer

*In addition, the following undesirable effects have occurred during post-marketing:*

- Dizziness, seizures
- Serious skin disorders including Stevens–Johnson syndrome and toxic epidermal necrolysis
- Dyspepsia (indigestion), vomiting
- Leukopenia (reduced white blood cells)
- Body as a Whole: Anaphylaxis (severe allergic reaction) including angioedema (swelling under the skin), face edema (facial swelling), itching and hives.
- Liver failure, hepatitis (inflammation of the liver), hepatocellular necrosis (death of liver cells), jaundice

(yellowing of the skin caused by the build up of bile.)

- High cholesterol and triglycerides,
- Hypokalemia (low potassium levels)
- Taste disturbances

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting).

#### **Storage and Disposal of STALENE 200**

##### -Storage

Store at temperature of not more than 30°C

##### -Disposal

Shelf – life: Two (2) years

#### **Product Description**

##### -What it looks like

White powder in plain, opaque blue and purple capsule

##### -Ingredients

-Active ingredient: Fluconazole

-Inactive ingredients:

Corn starch, Lactose anhydrous, Croscarmellose sodium, Sodium starch glycolate, Magnesium stearate

##### -MAL number:

MAL06061691AZ

#### **Manufacturer**

UNISON LABORATORIES CO., LTD.  
39 Moo 4, Klong Udomcholjorn, Muang Chachoengsao, Chachoengsao 24000 Thailand

#### **Product Registration Holder**

MEDISPEC (M) SDN.BHD  
# 55 & 57 Lorong Sempadan 2, (Off Boundary) 11400 Ayer Itam, Penang, Malaysia

#### **Date of Revision**

8/04/2015

#### **Serial Number:**

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