

## PATIENT INFORMATION LEAFLET:

### MYCODEAL SOLUTION

#### {Bifonazole 1% w/v}

*Read this leaflet carefully before you start taking this medicine.*

-Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor, health care provider or pharmacist.

-This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

1. What Mycodeal solution is and what it is used for.
2. Before you use Mycodeal solution.
3. How to use Mycodeal solution.
4. Possible side effects.
5. How to store Mycodeal solution.
6. Further information.

#### 1. WHAT MYCODEAL IS AND WHAT IT IS USED FOR

Mycodeal belongs to the class of medicines called imidazoles. It is an antifungal. It is used to treat fungal skin infections e.g. athlete's foot.

#### 2. BEFORE YOU USE MYCODEAL SOLUTION

##### Do not use Mycodeal

-If you are allergic (hypersensitive) to bifonazole or any of the other ingredients in these preparations.

-To treat nappy rash. Consult your doctor for cases of nappy rash.

-To treat nail, scalp and vaginal infections.

*Talk to your doctor or pharmacist before using Mycodeal*

-If you are not sure you have a fungal infection or athlete's foot.

-If you are using other medicines especially warfarin.

-If you are pregnant or breastfeeding.

##### Warnings and precautions

*Talk to your doctor or pharmacist before using Mycodeal if you have*

- had an allergic reaction to any other medicine to treat fungal infections such as econazole, clotrimazole, miconazole

- Diabetes

- Use with care on broken or raw skin.

- Do not cover the area with a bandage after you have applied mycodeal.

- Avoid getting mycodeal in the eyes.

- Do not swallow the medicine.

Nail bed treatment with Mycodeal requires that you firstly remove the infected nail using a local treatment, such as urea ointment.

##### Children and adolescents

Mycodeal should only be used on infants and children if it is prescribed for them by a doctor. Please ensure that no drug finds its way into the infant's mouth.

##### Other medicines and mycodeal

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Patients who are taking warfarin to prevent or treat clots must have their warfarin blood test monitored carefully by a doctor while using mycodeal.

##### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- Pregnancy: Mycodeal is not recommended to be used during pregnancy or in women who might conceive unless appropriate contraception measures are taken.

- Breast-feeding: Discontinue breast-feeding while using mycodeal.

##### Driving and using machines

Mycodeal has no influence on the ability to drive and use machines.

### 3. HOW TO USE MYCODEAL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This preparation is for external use only. Do not put in mouth or swallow.

Before each use wash the affected skin areas to remove loose flakes of skin and any residue from the previous treatment. After washing, dry the areas thoroughly, especially hard-to-reach areas such as between the toes.

Apply thinly and evenly to the affected areas rubbing in gently.

Apply once daily preferably at night for 2-3 weeks.

An antifungal dusting powder may be used with this preparation after consultation with a doctor.

If symptoms do not improve after 7 days consult a doctor

To aid in treatment;

-Despite the itching, do not scratch affected area.

-Keep the area clean and dry

-Do not share contact items e.g. towels, clothing to prevent spread of infection. Wash clothing items in contact e.g. socks, thoroughly and with hot water

-Wash hands after touching affected areas

#### WARNING

If you accidentally swallow see doctor immediately. If you accidentally get preparation in eyes or mouth, wash immediately then consult a doctor.

As this medicine may make you feel dizzy, you should not drive or operate machinery until you know how the drug affects you.

**If you use more Mycodeal Solution than you should.**

If you apply too much Mycodeal, contact your doctor or pharmacist.

**If you forget to use Mycodeal Solution.**

Apply as soon as you remember then continue with treatment as usual. Do not use a double dose to make up for a forgotten dose.

**If you stop using Mycodeal Solution.**

If you interrupt the treatment with Mycodeal or end it too soon, the infection may not be fully cleared and may come back again.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Mycodeal can cause side effects, although not everybody gets them.

*Stop using Mycodeal and see a doctor or go to a hospital straight away:*

If you develop an allergic reaction usually presented by either of the following: rash; swallowing or breathing problems; swelling of lips, tongue, face or throat; dizziness; nausea.

**It is expected that the following side effects may occur:**

Slight irritation or burning; peeling; reddening skin; soft appearance; swelling.

**However, tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days.**

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

#### 5. HOW TO STORE MYCODEAL

Do not store above 30°C. Store in the original container/carton in a cool dry place protected from direct sunlight.

Keep out of sight and reach of children.

Use only up to the Expiry date shown on Label or Package. Expiry date means the last date of that month indicated on the label.

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

#### 6. FURTHER INFORMATION:

*What Mycodeal Solution contains.*

The Active substance is Bifonazole 1%w/v.

The other ingredients are Ethanol and Isopropyl myristate.

*What Mycodeal Solution looks like and contents of the pack.*

A clear and colourless liquid free from any visible impurities in 15ml HDPE bottle with a nozzle in a unit box.

Further information on this product can be obtained from the regulatory department of Biodeal Laboratories Ltd.

[regulatoryaffairs@biodealkenya.com](mailto:regulatoryaffairs@biodealkenya.com)



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