CLONEA CLOTRIMAZOLE THRUSH TREATMENT 6 DAY CREAM

contains the active ingredient (clotrimazole)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Clonea Clotrimazole Thrush Treatment 6 Day Cream.

It does not contain all of the available information. It does not take the place of talking to our doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist. Keep this leaflet with your medicine.

You may need to read it again.

What is Clonea Clotrimazole Thrush Treatment 6 Day Cream used for?

Clonea Clotrimazole Thrush Treatment 6 Day Cream belongs to a class of drugs called antifungals and is used to treat vaginal yeast infections such as Candida (thrush). Candida infections result from an overgrowth of yeast fungus and cause an imbalance of the natural microorganisims that are present in the vagina. Certain illnesses such as diabetes, obesity and fatigue can increase the likelihood of infection.

Additionally hormonal changes during pregnancy, during certain times of the menstrual cycle, or due to the oral contraceptive pill, may also increase the chances of infection. Certain medications such as antibiotics and steroids may cause overgrowth of Candida.

Before using Clonea Clotrimazole Thrush Treatment 6 Day Cream

When you should not use this medicine: Do not use this medicine if you have ever had an allergic reaction to:

- clotrimazole or other antifungals
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include swelling of the parts of the body to which treatment has been applied; rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist.

Before you start to use it

See your doctor if:

- You are unsure whether you have thrush or this is the first time you have had thrush
- You are under 18 years of age
- You have had 3 or more infections in the last 6 months
- You have allergies to any other topical treatments

Tell your doctor if you are pregnant or think you might be.

You should see your doctor if you suspect you have thrush in the first three months of your pregnancy. Your doctor can discuss with you the risks and benefits involved with treatment.

Tell your doctor if you are breastfeeding and want to use this treatment.

It is not known whether the active ingredient, clotrimazole, is excreted in breast milk. Your

doctor will be able to discuss with you the risks or benefits involved in treatment.

Tell your doctor if you are diabetic.

Thrush in diabetics can mean that your blood sugar levels are not well controlled. Your doctor will be able to check this for you and advise treatment.

If you have not told your doctor about any of the above, tell him/her before you start using Clonea Clotrimazole Thrush Treatment 6 Day Cream.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking tacrolimus, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system.

How to use Clonea Clotrimazole Thrush Treatment 6 Day Cream

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions below, or on the box, ask your doctor or pharmacist for help.

How to use it

Wash your hands thoroughly before handling the cream or using the applicator.

To avoid the possibility of re-infection, strict personal hygiene must be observed.

The cream should preferably be inserted in the evening, just before bed time, with the use of an applicator.

Using it before you go to sleep will have the best effect.

Use a new applicator for each nightly dose.

Loading the applicator

- 1. Wash your hands thoroughly.
- 2. Pull out the plunger of the disposable applicator until it stops.
- 3. Remove cap from the tube of cream. If opening the tube for the first time, pierce the seal on the tube by inverting the cap over the end of the tube and pressing. Remove cap and set aside.
- 4. Screw the open end of the applicator to the tube.
- Squeeze the tube of cream until the applicator is full. The applicator will then hold approximately 5 grams of cream.
- 6. Unscrew the applicator from the tube and replace the cap on the tube.

Inserting the applicator

- Gently insert the applicator (open end first) as deeply into the vagina as possible. This is best done by lying on the back with the knees bent.
- Hold the applicator in position and slowly push the plunger with the forefinger until it stops. This places the cream into the vagina.
- 9. Remove the applicator from the vagina and dispose of the applicator.

How long to use it

Your treatment pack contains a tube of cream containing 35g of clotrimazole cream and six applicators. 5 grams (1 applicator-full) of cream should be inserted in the vagina daily for six consecutive days.

Continue using this medicine even if your symptoms disappear. It is important that the entire course is completed as advised for the treatment to be effective.

If you miss a dose, continue with the next dose as soon as you remember, or the next evening.

If you are not sure what to do, ask your doctor or pharmacist.

While you are using Clonea Clotrimazole Thrush Treatment 6 Day Cream

Things you must do

Discontinue treatment and tell your doctor or pharmacist if you develop a local reaction to this product.

See your doctor if the symptoms are not gone within 4 days.

See your doctor if symptoms return after completion of the course.

Things you must not do

Do not use Clonea Clotrimazole Thrush Treatment 6 Day Cream to treat any other complaints unless your doctor tells you to.

Do not give your treatment to anyone else, even if you suspect they have the same conditions as you.

Do not stop using this medicine until you have completed the course.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Preferably the treatment should be timed to avoid the menstrual period. This will allow the treatment to be most effective.

Ask your doctor if you have any questions about this.

Clonea Clotrimazole Thrush Treatment 6 Day Cream may reduce the effectiveness and safety of latex products, such as condoms and diaphragms, if it comes into contact with them.

Therefore, you should prevent Clonea Clotrimazole Thrush Treatment 6 Day Cream from coming into contact with these products. If Clonea Clotrimazole Thrush Treatment does accidentally come into contact with a condom or diaphragm, then replace the condom or diaphragm before using as contraception.

Things that may help you resolve

Thrush

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- Blot with toilet paper after urinating (instead of wiping back to front).
- Change underwear, night attire, towels and linen daily.

Avoid where possible:

- Perfumed toilet paper
- Fragrant soaps and bath oils
- Wearing tight or synthetic clothing

1

• Douches or vaginal deodorants

- Soaking baths
- Using tampons while using clotrimazole.

Side effects

Tell your doctor or pharmacist if you experience discomfort while you are using Clonea Clotrimazole Thrush Treatment 6 Day Cream.

This medicine helps most people with thrush but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Skin reaction to the cream (stinging, redness, blistering, peeling, swelling, itching)
- · Pain in the abdomen or pelvic area

Tell your doctor immediately or go to Accident and emergency at your nearest hospital if your experience any of the following:

- Rash
- Swallowing or breathing problems
- Swelling of your lips, face, throat or tongue
- Nausea, weakness, feeling dizzy or faint

Any of the above may be signs of an allergic reaction. Your doctor or pharmacist may recommend you discontinue treatment if you experience these effects.

After using Clonea Clotrimazole Thrush Treatment 6 Day Cream

Storage

Keep your cream in the tube until it is time to use it.

If you take the cream out of the tube it may not keep well.

Keep your cream in a cool dry place where the temperature stays below 25°C.

Keep all medicines away from children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Expiry

Check the expiry date marked on the end panel of the carton and on the crimp at the end of the tube which refers to the month and year of the expiration, e.g. 11 96 refers to the eleventh month of 1996. Do not use after the expiry date.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any cream that is left over.

Discard the cream out of reach of children.

Product description

What it looks like

White opaque cream in a 35g tube with six single use disposable applicators.

Ingredients

The active ingredient is Clotrimazole 10 mg/g. This cream also contains the following inactive ingredients:

- Propylene glycol
- Cetomacrogol 1000
- Cetostearyl alcohol
- CLONEA CLOTRIMAZOLE THRUSH TREATMENT 6 DAY CREAM MIMS/myDr November 2016

- Liquid paraffin
- Dimethicone 100
- White soft paraffin
- Glyceryl monostearate SE
- Benzyl alcohol
- Disodium edetate
- Purified-water.

Sponsor

Alphapharm Pty Limited (ABN 93 002 359 739) Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Phone: (02) 9298 3999 www.alphapharm.com.au AUST R 267255

This leaflet was prepared in November 2015.