

## PATIENT INFORMATION LEAFLET

### CANDID – V Gel Clotrimazole USP 2% w/w

**Read all of this leaflet carefully before you start using 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 gets 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**

- a) What Candid – V Gel is and what is it used for?**
- b) Before you use Candid – V Gel**
- c) How to use Candid – V Gel**
- d) Possible side effects**
- e) How to store Candid – V Gel**
- f) Further information**

#### **a. What Candid – V Gel is and what is it used for?**

Candid – V Gel relieves irritation of the vulva (vulvitis) which is caused by vaginal thrush (candidiasis).

Although this gel provides relief from the external irritation caused by vaginal thrush, it cannot treat any internal (vaginal) cause of the infection.

Ask your doctor or pharmacist to recommend a treatment for this.

**Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.**

Some women suffer from recurrent attacks of thrush.

To reduce the frequency of these attacks, the sexual partner's penis can be treated with this gel to prevent re-infection, even if they have no symptoms of thrush.

The active substance in Candid – V Gel is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

#### **b. Before you use Candid – V Gel**

##### **Do not use Candid – V Gel**

If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients

**Take special care with Candid – V Gel:**

- If you are unsure whether you have thrush or this is the first time you have had these symptoms.
- If you have had more than two infections of thrush in the last six months.
- If you or your partner have ever had a sexually transmitted disease.
- If you are aged under 16 or over 60.
- If you have ever had an allergic reaction to Candid V Gel or any other vaginal antifungal products.
- If you have any of the following symptoms:
  - Irregular vaginal bleeding.
  - Abnormal vaginal bleeding or a blood stained discharge.
  - Ulcers, blisters or sores of the vagina or vulva.
  - Lower abdominal pain.
  - Pain or difficulty in passing urine.
  - Fever or chills.
  - Feeling sick or vomiting.
  - Diarrhoea.
  - A foul smelling discharge from the vagina.

This is because Candid – V Gel may not be the right treatment for you.

**Using with other medicines:**

As with other gels, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

**Pregnancy and breast-feeding:**

Candid – V Gel can be used in pregnancy and breastfeeding.

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Candid – V Gel. If you have informed your doctor or midwife already, follow his/her instructions carefully.

**Driving and using machines**

Clotrimazole has no or negligible influence on the ability to drive or use machines.

**c. How to use Candid – V Gel****Women:**

If Candid – V Gel has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
- To treat the itching and soreness of the vulva (vulvitis), the gel should be thinly and evenly applied to the area around the entrance of the vagina, 2 or 3 times a day and smoothed in gently. A product to treat the internal (vaginal) infection should be used at the same time.

Treatment should be continued until symptoms of the infections disappear. Consult your doctor if the symptoms of your infection do not improve within seven days of finishing treatment for the internal infection.

**Treating your sexual partner:**

If your sexual partner is treated with this gel, the gel should be applied to the end of the penis 2 or 3 times a day for up to two weeks.

**Candid – V Gel is for external use only.****Do not put the gel in your mouth or swallow it.**

If the gel is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

**d. Possible side effects**

Like all medicines, Candid – V Gel can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the gel. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

Signs of an allergic reaction may include:

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

After you apply the gel you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, redness, irritation, pins and needles, or peeling of skin

If you experience any of the above effects or react badly to the gel in any other way not listed in this leaflet, tell your doctor or pharmacist immediately.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

**e. How to store Candid – V Gel****Keep out of the reach and sight of children.**

This product should be stored in the original carton.

Store below 30°C. Protect from freezing & light.

Do not use Candid – V Gel after the expiry date which is stated at one end of the carton and on the end of the tube of gel. The expiry date refers to the last day of that month.

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.

**f. Further information**

**What Candid – V Gel contains:**

- The active substance is clotrimazole at a strength of 2% w/w.
- The other ingredients are Inactive ingredients are Chlorocresol, Carbomer 940 (Carbopol 940), cetyl Alcohol, Cetomacrogol Emulsifying Wax, propylene Glycol, Glycerine Refined, Benzyl Alcohol, Sodium Hydroxide, Purified water.

See Section 2 ‘Do not use’ and ‘Important information about some of the ingredients’ for chlorocresol, cetyl alcohol, and propylene glycol advice.

**What Candid –V Gel looks like and contents of the pack:**

A printed carton containing a leaflet, applicator and a printed aluminum collapsible tube containing white semisolid smooth gel

**Name and full physical address of Marketing Authorization Holder and Manufacturing site:**

**Marketing authorisation holder:**

Glenmark Pharmaceuticals Limited, B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai- 400 026, (India).

**Manufacturing site:**

Glenmark Pharmaceuticals Limited, Plot No. E-37, 39, D-Road, MIDC, Satpur, Nashik – 422007, Maharashtra, India

**For any information about this medicinal product, please contact the Wessex Pharmaceuticals (Rwanda) Ltd - local representative of the supplier:**

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**This leaflet was last approved in**

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**DOCUMENT REVISION HISTORY**

| Date of Revision | Revision Number | Document Number | Change Made  |
|------------------|-----------------|-----------------|--------------|
| November 2017    | 00              | Not Applicable  | First Issue  |
| April 2023       | 01              | Not Applicable  | Second Issue |