SUMMARY OF PRODUCT CHARACTERISTICS

CANDID V GEL
Clotrimazole Vaginal Gel

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Candid-V Gel (Clotrimazole Vaginal Gel)

1.1 Strength

Clotrimazole USP…….2% w/w

1.2 Pharmaceutical Form

Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gm contains
Clotrimazole USP 2% w/w
For list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel

Visual Description: White semisolid smooth gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clotrimazole Vaginal Gel is recommended for the treatment of candidal vulvitis. It should be used as an adjunct to treatment of candidal vaginitis.

It can also be used for treatment of the sexual partner's penis to prevent re-infection.

4.2 Posology and Method of Administration

Clotrimazole Vaginal Gel should be applied to the vulva and surrounding area.

It can also be applied to the sexual partner's penis to prevent re-infection.

Posology
Adults
The gel should be applied thinly two or three times daily and rubbed in gently.

Treatment should be continued until symptoms of the infection disappear. However, if after concomitant treatment of the vaginitis, the symptoms do not improve within seven days, the patient should consult a doctor.

If the gel is being used for treatment of the sexual partner's penis it should be applied two or

three times daily for up to two weeks.

Special populations

a. ***Elderly population:*** No data available
b. ***Renal Impairment:*** No data available
c. ***Hepatic Impairment:*** No data available
d. ***Patients with a particular genotype:*** No data available
e. ***Other relevant special population (patients with other concomitant disease or overweight patients):*** No data available

Paediatric population

Children

There is no clinical experience in the use of Clotrimazole Vaginal Gel in children.

4.3 Method of administration

Refer above section 4.2.

4.4 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.5 Special Warnings and Precautions for Use

Medical advice should be sought if this is the first time the patient has experienced symptoms of candidal vaginitis.

Before using Clotrimazole Vaginal Gel medical advice must be sought if any of the following are applicable:

- more than two infections of candidal vaginitis in the last six months
- previous history of a sexually transmitted disease or exposure to partner with sexually transmitted disease
- pregnancy or suspected pregnancy
- aged under 16 or over 60 years
- known hypersensitivity to imidazoles or other vaginal antifungal products

Clotrimazole Vaginal Gel should not be used if the patient has any of the following symptoms whereupon medical advice should be sought:

- irregular vaginal bleeding
- abnormal vaginal bleeding or a blood-stained discharge
- vulval or vaginal ulcers, blisters or sores
- lower abdominal pain or dysuria
- any adverse events such as redness, irritation or swelling associated with the treatment
- fever or chills
- nausea or vomiting
- diarrhoea
- foul smelling vaginal discharge

4.6 Paediatric population

Not available.

4.7 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.8 Additional information on special populations

Not available.

4.9 Paediatric population

Not available.

4.10 Fertility, Pregnancy and Lactation

4.10.1 General principles

There is a limited amount of data from the use of clotrimazole in pregnant women.
Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted.

4.10.2 Women of childbearing potential / Contraception in males and females

None stated.

4.10.3 Pregnancy

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

4.10.4 Breastfeeding

There are no data on the excretion of clotrimazole into human milk. However, systemic absorption is minimal after administration and is unlikely to lead to systemic effects. Clotrimazole may be used during breastfeeding.

4.10.5 Fertility

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.11 Effects on ability to drive and use machines

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

4.12 Undesirable effects

a) Summary of the safety profile

Frequency not known. As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible

Immune system disorder: anaphylactic reaction, angioedema, hypersensitivity

Vascular disorder: syncope, hypotension

Respiratory, thoracic and mediastinal disorders: dyspnea

Skin and subcutaneous tissue disorders: blister, dermatitis contact, erythema, paraesthesia, skin exfoliation, pruritus, rash, urticaria, stinging skin/burning sensation skin.

General disorders and administration site conditions: application site irritation, application site reaction, oedema, pain.

b) Tabulated list of adverse reactions: No tabulated list available

c) Description of selected adverse reactions: No data available

d) Paediatric population: No data available

e) Other special populations: No data available

f) Further guidance on the estimation of frequency of adverse reactions
Adverse reactions from clinical trials: Not available
Adverse reactions from safety studies: Not available
Adverse reactions from spontaneous reporting: Not available

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.13 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

Additional information on special populations: No data available

Paediatric population: No data available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamics properties describe:
Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives

ATC Code: D01A C01

Mechanism of Action:

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophytes, yeasts, moulds, etc.

Pharmacodynamic effects
Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is primarily fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, clotrimazole also acts on gram-positive microorganisms (*Streptococci* / *Staphylococci* / *Gardnerella vaginalis*), and gram-negative microorganisms (Bacteroides).

In vitro clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of *Enterococci* - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

Clinical efficacy and safety
No data available.

5.2 Pharmacokinetic properties

a. General introduction
Not applicable

b. General characteristics of the active substance(s)
Absorption:
Pharmacokinetic investigations after dermal application have shown that clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of clotrimazole were below the detection limit of 0.001 µg/ml, suggesting that clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

Distribution:
No data available

Biotransformation:
No data available

Elimination:
No data available

Linearity/non-linearity:
No data available

c) Characteristics in specific groups of subjects or patients
No data available

d) Pharmacokinetic/ pharmacodynamic relationship(s)
No data available

Paediatric population: No data available

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients are Chlorocresol, Carbomer 940 (Carbopol 940), cetyl Alcohol, Cetomacrogol Emulsifying Wax, propylene Glycol, Glycerine Refined, Benzyl Alcohol, Sodium Hydroxide, Purified water.

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Aluminium collapsible tube of 30g

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORISATION HOLDER ADDRESS:
Glenmark Pharmaceuticals Limited
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai Road Mumbai- 400 026, INDIA

MANUFACTURING SITE ADDRESS:
Plant /Site: Glenmark Pharmaceuticals Limited
Plot No. E-37, 39, D-Road, MIDC, Satpur, Nashik 422007,
Maharashtra State, India.

8. MARKETING AUTHORISATION NUMBER(S)

NA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE REGISTRATION

NA

10. DATE OF REVISION OF THE TEXT

April 2023

11. 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