Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

Clotvagy-100 (Clotrimazole Vaginal Inserts USP 500mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Vaginal insert contains:

Clotrimazole USP 100mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Vaginal Insert

White to off white, elongated, bullet shape  uncoated vaginal inserts.

4.0 Clinical particulars

4.1 Therapeutic Indications

Clotrimazole vaginal tablets are indicated for the treatment of candida vaginitis.

Posology

The treatment consists of one vaginal tablet to be inserted in the evening.

Method of administration

The tablet is placed into the holder of the applicator provided. The applicator is inserted into the vagina as deeply as is comfortable. This is best achieved when lying on the back with the legs slightly bent. The plunger is slowly pushed in as far as it will go depositing the tablet in the vagina. The applicator should then be removed from the vagina and disposed of carefully, out of the reach of children.

As a matter of practicality the treatment should not be undertaken during menstruation.

If the external symptoms of the disease (e.g. discharge, itching) have not subsided completely within three days after termination of therapy, treatment should be continued only after consulting the attending doctor.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 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 tablet, medical advice must be sought if any of the following are applicable:

- more than two infections of candidal vaginitis in the last 6 months.
- previous history of 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 tablet should not be used if the patient has any of the following symptoms where upon 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.

Patients should be advised to consult their physician if the symptoms have not been relieved within one week of using Clotrimazole vaginal tablet. Clotrimazole vaginal tablet can be used again if the candidal infection returns after 7 days. However, if the candidal infection recurs more than twice within six months, patients should be advised to consult their physician.

4.5 Interaction with other medicinal products and other forms of interaction

Clotrimazole reduces the efficacy of other drugs which are used for the treatment of fungal diseases (amphotericin and other polyene antibiotics, e.g. nystatin).

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. Concomitant medication with Clotrimazole vaginal tablet and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels. Patients should thus be closely monitored for signs and symptoms of tacrolimus or sirolimus overdosage, if necessary by determination of the respective plasma levels.

4.6 Pregnancy and lactation

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.

Pregnancy

In animal studies, clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following vaginal treatment, harmful effects with respect to reproductive toxicity are not predicted.

There are limited amount of data from the use of clotrimazole in pregnant women.

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

During pregnancy, the vaginal tablet can be inserted without using an applicator.

Breast-feeding

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

This medication has no or negligible influence on the ability to drive or use machinery.

4.8 Undesirable effects

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

Immune system disorders:

Allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus)

Rarely patients may experience local mild burning or irritation immediately after applying the vaginal tablet. Very rarely, the patient may find this irritation intolerable and stop treatment. Hypersensitivity reactions may occur.

Reproductive system and breast disorders:

Genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

Gastrointestinal disorders:

Abdominal pain

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 via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA

4.9 Overdose

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

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). It should be carried out only if the airway can be protected adequately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

The antimycotic effect of clotrimazole is primarily fungistatic, and at high concentrations also fungicidal. Clotrimazole is only effective against proliferating fungi; fungal spores are only slightly sensitive, in-vitro.Current knowledge indicates that the antimycotic effect of clotrimazole is due to inhibition of ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

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

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.

5.2 Pharmacokinetic properties

Absorption of Clotrimazole from the vagina following administration as a vaginal tablet is 3-10%. Fungicidal concentrations of clotrimazole are found in the vaginal fluid up to 3 days after the application of one 500 mg vaginal tablet. In contrast plasma levels of clotrimazole up to 72 hours after application are lower than 0.01 μg/ml, demonstrating that clotrimazole is rapidly metabolised and does not lead to measurable systemic effects or side effects..

Binding of clotrimazole to blood serum proteins is about 98% in the undiluted serum, due to its highly hydrophobic properties.

Clotrimazole is metabolised in the liver via oxidation and degradation of the imidazole cycle (desamination, O-desalkylation). Thus inactive hydroxy derivatives occur. These agents are mainly excreted via the gallbladder with the faeces.

The elimination half-life of clotrimazole is 3.5-5 hours.

5.3 Preclinical safety data

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6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Lactose, Maize starch, Purified Talc, Magnesium stearate, Sodium Starch Glycolate (Type A), Colloidal Anhydrous Silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

6 Tablets (Inserts) packed in printed strip aluminium foil and such 1 Strip are packed in unit carton along with packing insert.

6.6 Special precautions for disposal

The vaginal tablet is to be taken out of the aluminium package and inserted into the form of the disposable applicator.

The disposable applicator is to be inserted into the vagina as deep as possible.

By carefully pushing the inner plunger as far as it will go, the vaginal tablet is placed in the vagina.

After usage the disposable applicator is to be removed from the vagina and safely disposed of out of the reach of children.

Use of the vaginal tablet in combination with the disposable applicator.

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

7. MARKETING AUTHORISATION HOLDER

MEDICAMEN Biotech Limited

SP-1192 A&B, PHASE - IV,

Industrial Area,

Bhiwadi - 301 019

Distt. Alwar,

Rajasthan, India.

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

Certificate No: 08528/09814/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION]

Mar 30, 2023

10. DATE OF REVISION OF THE TEXT

August 2023