



AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)



CIN: 11-09913

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauripada, Vasai (E), Dist. Thane - 401 208, INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Brand Name : MICLOGEN Generic Name : Miconazole Nitrate, Clobetasol and Gentamicin Cream	2021
Module 1 1.5	Administrative Information and Product Information Product Information
	Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Miconazole Nitrate, Clobetasol and Gentamicin Cream

1.1 (Trade) name of product

MICLOGEN

1.2 Strength

Miconazole Nitrate BP 2 % w/w
Clobetasol Propionate BP 0.05 % w/w
Gentamicin Sulphate BP Eq. to Gentamicin 0.1 % w/w

1.3 Pharmaceutical Dosage Form

External application

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2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Miconazole Nitrate BP 2 % w/w

Clobetasol Propionate BP 0.05 % w/w

Gentamicin Sulphate BP Eq. to Gentamicin 0.1 % w/w

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / Tab.
<u>ACTIVE</u>				
Miconazole Nitrate	BP	2% w/w	5.00%	315 mg
Gentamicin as Gentamicin Sulphate	BP	0.1 % w/w	15.00%	17.25 mg
Clobetasol Propionate	BP	0.05% w/w	5.00%	7.89 mg
<u>NON ACTIVE</u>				
Propylene Glycol	BP	-	-	1440 mg
White Soft Paraffin	BP	-	-	900 mg
Liquid Paraffin Light	BP	-	-	1200 mg
Cetomacrogol-1000	BP	-	-	525 mg
Cetostearyl Alcohol	BP	-	-	1200 mg
Chlorocresole	BP	-	-	15 mg
Disodium E.D.T.A.	BP	-	-	15 mg
Sodium Metabisulphite.	BP	-	-	15 mg

BP = British Pharmacopoeia.



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3. PHARMACEUTICAL DOSAGE FORM

15 GM TUBE IN A CARTON

Off white, homogenous, smooth cream free from grittiness.



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4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Miconazole, sold under the brand name **Monistat** among others, is an antifungal medication used to treat ring worm, pityriasis versicolor, and yeast infections of the skin or vagina. It is used for ring worm of the body, groin (jock itch), and feet (athlete's foot). It is applied to the skin or vagina as a cream or ointment.

Common side effects include itchiness or irritation of the area in which it was applied.^[2] Use in pregnancy is believed to be safe for the baby. Miconazole is in the imidazole family of medications. It works by decreasing the ability of fungi to make ergosterol, an important part of their cell membrane. Miconazole was patented in 1968 and approved for medical use in 1971. It is on the World Health Organization's List of Essential Medicines.

Clobetasol Propionate is the propionate salt form of clobetasol, a topical synthetic corticosteroid with anti-inflammatory, anti-pruritic, and vasoconstrictive properties. Clobetasol propionate exerts its effect by binding to cytoplasmic glucocorticoid receptors and subsequently activates glucocorticoid receptor mediated gene expression. This results in synthesis of certain anti-inflammatory proteins, while inhibiting the synthesis of certain inflammatory mediators. Specifically, clobetasol propionate appears to induce phospholipase A2 inhibitory proteins, thereby controlling the release of the inflammatory precursor arachidonic acid from membrane phospholipids by phospholipase A2.

Gentamicin, sold under brand name **Garamycin** among others, is an antibiotic used to treat several types of bacterial infections.^[3] This may include bone infections, endocarditis, pelvic inflammatory disease, meningitis, pneumonia, urinary tract infections, and sepsis among others.^[3] It is not effective for gonorrhea or chlamydia infections.^[3] It can be given intravenously, by injection into a muscle, or topically.^[3] Topical formulations may be used in burns or for infections of the outside of the eye.^[4] It is often only used for two days until bacterial cultures determine what specific antibiotics the infection is sensitive to.^[5] The dose required should be monitored by blood testing. Gentamicin can cause inner ear problems and kidney problems.^[3] The inner ear problems can include problems with balance and hearing loss.^[3] These problems may be permanent.^[3] If used during pregnancy, it can cause harm to the developing baby.^[3] However, it appears to be safe for use during breastfeeding.^[6] Gentamicin is a type of aminoglycoside.^[3] It works by disrupting the ability of the bacteria to make proteins, which typically kills the bacteria.^[3] Gentamicin is naturally produced by the bacterium *Micromonospora purpurea*,^[7]^[3] was patented in 1962, approved for medical use in 1964.^[8] The antibiotic is collected from the culture of the *Micromonospora* by perforating the cell wall of the bacterium. Current research is underway to understand the biosynthesis of this antibiotic in an attempt to increase



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expression and force secretion of Gentamicin for higher titer. Gentamicin is currently on the World Health Organization's List of Essential Medicines.^[9] The World Health Organization classifies gentamicin as critically important for human medicine.^[10] It is available as a generic medication.^[11]

4.2 Posology and Method of Administration

Method of administration: External application

4.3 Contraindications

Miconazole is contraindicated for people who use certain drugs that are metabolized by CYP3A4, for the reasons mentioned above:^[7]

- drugs that also prolong the QT interval because of potential problems with the heart rhythm
- ergot alkaloids
- statins
- triazolam and oral midazolam
- sulfonamides with a potential to cause hypoglycaemia (low blood sugar)

Gentamicin should not be used if a person has a history of hypersensitivity, such as anaphylaxis, or other serious toxic reaction to gentamicin or any other aminoglycosides.^[13] Greater care is required in people with myasthenia gravis and other neuromuscular disorders as there is a risk of worsening weakness.

According to the California Environmental Protection Agency, **clobetasol propionate** should not be used by pregnant women, or women expecting to become pregnant soon, as studies with rats shows a risk of birth defects:

"Studies in the rat following oral administration at dosage levels up to 50 mcg/kg per day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose. Pregnancy: **Teratogenic** Effects (i.e., possibility of causing abnormalities in fetuses): Pregnancy Category C: Clobetasol propionate has not been tested for teratogenicity when applied topically; however, it is absorbed percutaneously, and when administered subcutaneously it was a significant teratogen in both the rabbit and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. There are no adequate and well-controlled studies of the teratogenic effects of clobetasol propionate in pregnant women. Temovate Cream and Ointment should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus."



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4.4 Special Warnings and Precautions for Use

Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops, treatment with Gentamicin Sulfate Ointment USP, 0.1% should be discontinued and appropriate therapy instituted.

4.5 Use in Pregnancy and Lactation

Patients are instructed to consult with their physician if they experience severe adverse reaction, they become pregnant or intend to become pregnant or they have any other questions.

4.6 Effects on ability to drive and operate machine

People can drive or use machines after taking **MICLOGEN**.

4.7 Overdoses

If irritation develops, use of ointment should be discontinued and appropriate therapy instituted.



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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacokinetic Properties

Miconazole Nitrate

After application to the skin, miconazole can be measured in the skin for up to four days, but less than 1% is absorbed into the bloodstream. When applied to the oral mucosa (and possibly also for vaginal use^[8]), it is significantly absorbed. In the bloodstream, 88.2% are bound to plasma proteins and 10.6% to blood cells. The substance is partly metabolized via the liver enzyme CYP3A4 and mainly eliminated via the faeces.^{[6][7]}

Gentamicin

Gentamicin is also used in molecular biology research as an antibacterial agent in tissue and cell culture, to prevent contamination of sterile cultures. Gentamicin is one of the few heat-stable antibiotics that remain active even after autoclaving, which makes it particularly useful in the preparation of some microbiological growth media.

Clobetasol Propionate

Corticosteroids bind to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals. Clobetasol propionate is generally applied twice daily so the duration of action is long. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces.^[A187463] Patients taking corticosteroids should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

DrugBank

Clobetasol Propionate is the propionate salt form of clobetasol, a topical synthetic corticosteroid with anti-inflammatory, anti-pruritic, and vasoconstrictive properties. Clobetasol propionate exerts its effect by binding to cytoplasmic glucocorticoid receptors and subsequently activates glucocorticoid receptor mediated gene expression. This results in synthesis of certain anti-inflammatory proteins, while inhibiting the synthesis of certain inflammatory mediators. Specifically, clobetasol propionate appears to induce phospholipase A2 inhibitory proteins, thereby controlling the release of the inflammatory precursor arachidonic acid from membrane phospholipids by phospholipase A2



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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Propylene Glycol	BP	1440 mg
White soft Paraffin	BP	900 mg
Liquid Paraffin Light	BP	1200 mg
Cetomacrogol -1000	BP	525 mg
Cetostearyl Alcohol	BP	1200 mg
Chlorocresole	BP	15 mg
Di Sodium E.D.T.A	BP	15 mg
Sodium Metabisulphite	BP	15 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.



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6.5 Nature and Contents of Container

15 gm tube in a carton.

30 gm tube in a carton.

7. Name and address for the marketing authorization holder

AGOG PHARMA LTD.

Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gaurapada,
Vasai (E), Dist. Thane,
India.

8. Marketing Authorisation Number: Rwanda FDA-HMP-MA-1392

9. Date of revision of the text: July 2024

Date:
Director of the manufacturer
(Signature, Full name, Stamp)

Date:
Director of applicant company
(Signature, Full name, Stamp)