1. NAME OF THE MEDICINAL PRODUCT

Brand Name : **DAMPHOS**
Generic Name : Clindamycin and Clotrimazole Vaginal Suppositories
Strength : 100 mg
Pharmaceutical Form: Suppository

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft gelatin vaginal suppository contains:

Clindamycin Phosphate	USP	
eq. to Clindamycin		100 mg
Clotrimazole	USP	100mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Vaginal Suppositories.
Pale yellow coloured, opaque, oval shaped, soft gelatin, vaginal suppositories containing white coloured viscous mass.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Infective leucorrhoea, mixed infections and non-specific vaginitis, Vaginal Candidiasis bactorial vaginosis & Trichomonasis.

4.2 Posology and method of administration

Suppositories should be inserted into the vagina for 7 consecutive nights. Preferably before retiring to bed. Treatment should be timed so as to avoid the menstrual period.
Directions for Use:
Wash hands thoroughly, before and after insertion of Damphos in the vagina. The suppository should be inserted as deep as possible. This is best achievedP when lying on the back with legs pulled in little towards the body. After the insertion of Damphos no activity should be done such as standing, walking, running etc; hence insert while retiring to bed. For best results, take the complete therapy of 7 days.

4.3 Contraindications

Damphos is contraindicated in individuals with a history of hyper-sensitivity to clindamycin,

lincomycin, clotrimazole or any of the components of this vaginal suppository. It is also contraindicated in individuals with a history of regional enteritis, ulcerative colitis, or a history of "antibiotic-associated" colitis.

4.4 Special warnings and precautions for use

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clindamycin, and may range in severity from mild to life-threatening. Orally and parenterally administered clindamycin has been associated with severe colitis, which may end fatally. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of Damphos, because approximately 30% of the clindamycin dose is systemically absorbed from the vagina.

4.5 Interation with other medicinal products and other forms ofinteractions

Systemic clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents. Concomitant medication with vaginal clotrimazole 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 overdosage, if necessary by determination of the respective plasma levels.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy. This drug should be used during the first trimester of pregnancy only if clearly needed.

Reproduction studies have been performed in rats and mice using oral and parenteral doses up to 600 mg/kg/day and have revealed no evidence of harm to the fetus. In one mouse strain, cleft palates were observed in treated fetuses; this outcome was not produced in other mouse strains or in other species and is, therefore considered to be a strain specific effect.

Lactation

Damphos has been detected in human milk after oral or parenteral administration. It is not known if damphos is excreted in human milk following the use of vaginally administered. Because of the potential for serious adverse reactions in nursing infants from damphos, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machine

No effects on ability to drive and use machines have been observed.

4.8 Undesirable effects

Local reactions including irritation and burning may occur in patients treated topically; contact allergic dermatitis has been reported.

4.9 Overdose

Not Applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Clindamycin phosphate binds exclusively to the 50S subunit of bacterial ribosomes and suppresses protein synthesis. It has antibacterial activity against gram-positive organisms and a lower order of activity against gram-negative organisms. In vitro activity does not necessarily imply in vivo efficacy. The in vitro spectrum of activity includes staphylococci (including penicllinase-producing strains), beta-haemolytic streptococci, Diplococcus pneumoniae, Clostridium perfringes, Corynebacterium acnes and Actinomyces israelli. Clindamycin phosphate is not active against most strains of Streptococcus faecalis, Escherichia coli, Shigella spp., Salmonella spp., Proteus spp., and Pseudomonas spp. The biological half-life of Clindamycin is 2.4 hours.

Clotrimazole has a fungicidal action on dermatophytes, yeasts, moulds and other fungi. Clotrimazole is an imidazole antifungal agent. Imidazoles inhibit 14-α-demethylation of lanosterol in fungi by binding to one of the cytochrome P-450 enzymes. This leads to the accumulation of 14-α methylsterols and reduced concentrations of ergosterol, a sterol essential for a normal fungal cytoplasmic membrane. The methylsterols may affect the electron transport system, thereby inhibiting growth of fungi. Clotrimazole has been shown to be active against most strains of the following dermatophytes, both in vitro and in clinical infections including Epidermophyton floccosum, Trichophyton mentagrophytes, and Trichophyton rubrum.

5.2 Pharmacokinetic properties

Clotrimazole

Pharmacokinetic investigations after vaginal application have shown that only a small amount of Clotrimazole (3- 10% of the dose) is absorbed. Due to the rapid hepatic metabolization of absorbed Clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of Clotrimazole after vaginal application of a 500mg dose were less than 10 ng/ml., suggesting that Clotrimazole applied intravaginally is unlikely to lead to measurable systemic effects or side effects.

Clindamycin

Following a once a day intravaginal dose of! 00 mg of clindamycin administered to 6 healthy female volunteers for 7 days, the administered dose was absorbed systemically. The peak serum clindamycin concentration observed on the first day averaged 18 ng/mL (range 4 to 47 ng/mL) and on day 7 it averaged 25 ng/mL (range 6 to 61 ng/mL). These peak concentrations were attained approximately IO hours post-dosing (range 4-2 4 hours).

Following a once a day intravaginal dose of 100 mg of clindamycin, administered for 7 consecutive days to 5 women, absorption was slower and less variable than that observed in healthy females. The peak serum clindamycin concentration observed on the first day averaged 13 ng/mL (range 6 to 34 ng/mL) and on day 7 it averaged 16 ng/mL (range 7 to 26 ng/mL).
These peak concentrations were attained approximately 14 hours post-dosing (range 4-24 hours). There was little or no systemic accumulation of clindamycin after repeated (7 day) vaginal dosing of clindamycin. The systemic half-life was l.5 to 2.6 hours.

5.3 Preclinical safety data

Not applicable

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light Liquid Paraffin
White soft paraffin
Gelatin
Glycerol
Liquid Sorbitol (Non- Crystallising)70%
Methyl Hydroxybenzoate
Propyl Hydroxybenzoate
Ethyl Vanillin
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C. Protected from light and moisture.
Keep out of reach of children.

6.5 Nature and contents of container

Blister Pack of 7 vaginal Suppositories.

6.6 Special precaution for disposal

None

7. APPLICANT/ HOLDER OF CERTIFICAE OF PRODUCT REGISTRATION

Name	:	UNOSOURCE PHARMA NIGERIA LIMITED,
Address	:	# 47 Babapomile Street, Onipetesi Estate, Mangoro-Lagos,Nigeria.
Phone	:	002348038540440
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8. DRUG PRODUCT MANUFACTURER

Name	:	Akums Drugs & Pharmaceuticals Ltd.
Address	:	19, 20, 21, Sector 6-A, IIE, SIDCUL, Ranipur, Haridwar-249403 Uttarakhand
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9. NAFDAC REGISTRATION NUMBER(S)

B4-8130

10. DATE OF REVISION OF THE TEXT

04/01/2025