## ACNIL- acnil clindamycin hydrochloride and metronidazole liniment liniment Jiangsu Chenpai Bond Pharmaceutical Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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DOSAGE AND ADMINISTRATION For external use only. Drip 1~2 drops of Acnil to affected area, or dip some Acnil in cotton bud and apply to the affected area. It should be applied three times daily. Two weeks' treatment constitutes a single therapeutic course. Repeat another therapeutic course if it is necessary.

ADVERSE REACTIONS: A few instance of local irritation or burning sensation may be observed. occasionally during the treatment. Allergic reaction can be observed rarely.

8.0 mg of Metronidazole.

PHARMACOLOGY AND TOXICOLOGY Clindamycin Hydrochloride is a bacteriostatic antibiotic, which is 4 to 8 times more potent than Lincomycin. It has potent antibacterial activity to aerobic gram-positive bacterium, such as Staphylococcus, Streptococcus, Bacillus diphtheriae and Bacillus anthracis. It also has good antibacterial activity to anaerobic gram-negative bacterium. Bacteroides (including bacteroides fragilis) and Clostridium are morbidly susceptible to it. It binds exclusively to the 50'S subunit of sensitive bacterial ribosome and suppresses protein synthesis. Clindamycin is a bacteriostat, but can kill high sensitive bacterium at high concentration. Metronidazole is an anti-anaerobic bacterial, anti-trichomonal and anti-amebic agent. Combination of Clindamycin Hydrochloride and Metronidazole can kill Propionibacterium acnes, Pityrosporum ovale, and some other sensitive bacterium and vermiform mite, and can inhibit them from growing. As a result, it can reduce the creation of lipase, and prevent triacylglycerol from hydrolyzing into free fatty acid.

INDICATIONS It is indicated for the treatment of acne (especially for the acne pustulosa, cystic acne), tympanitis, nasosinusitis, folliculitis, and other bacterial infection on skin. It is also indicated for the supportive treatment of seborrheic dermatitis and brandy nose.

WARNINGS: General: 1. If any irritation or other adverse reactions occurred, stop or reduce the drug, and consult a doctor. 2. It should not be used for long, because it may induce tolerance to bacterium. 3. Keep out of reach of children.

DESCRIPTION Acolorless or slightly yellow clear liquid; with an odour of alcohol.

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Drug Interactions: There is antagonism between ACNIL and erythromycin, so the combination of ACNIL and erythromycin is forbidden.

It is a compound preparation. Each milliliter contains 10.0 mg of Clindamycin Hydrochloride (calculated as Clindamycin),



# ACNIL

Clindamycin Hydrochloride and Metronidazole Liniment

It is a compound preparation. Each milliliter contains 10.0 mg of Clindamycin Hydrochloride (calculated as Clindamycin), and 8.0 mg of Metronidazole.

#### DESCRIPTION

A colorless or slightly yellow clear liquid; with an odour of alcohol.

#### PHARMACOLOGY AND TOXICOLOGY

Clindamycin Hydrochloride is a bacteriostatic antibiotic, which is 4 to 8 times more potent than Lincomycin. It has potent antibacterial activity to aerobic gram-positive bacterium, such as Staphylococcus, Streptococcus, Bacillus diphtheriae and Bacillus anthracis. It also has good antibacterial activity to anaerobic gram-negative bacterium. Bacteroides (including bacteroides fragilis) and Clostridium are morbidly susceptible to it. It binds exclusively to the 50°S subunit of sensitive bacterial ribosome and suppresses protein synthesis. Clindamycin is a bacteriostat, but can kill high sensitive bacterium at high concentration. Metronidazole is an anti-anaerobic bacterial, anti-trichomonal and anti-amebic agent. Combination of Clindamycin Hydrochloride and Metronidazole can kill Propionibacterium acnes, Pityrosporum ovale, and some other sensitive bacterium and vermiform mite, and can inhibit them from growing. As a result, it can reduce the creation of lipase, and prevent triacylglycerol from hydrolyzing into free fatty acid.

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#### DOSAGE AND ADMINISTRATION

For external use only. Drip 1-2 drops of Acnil to affected area, or dip some Acnil in cotton bud and apply to the affected area. It should be applied three times daily. Two weeks' treatment constitutes a single therapeutic course. Repeat another therapeutic course if it is necessary.

#### ADVERSE REACTIONS:

A few instance of local irritation or burning sensation may be observed occasionally during the treatment. Allergic reaction can be observed rarely.

#### CONTRAINDICATION:

- 1.It is contraindicated in patients with known hypersensitivity to any of its ingredients.
- 2.It is contraindicated in pregnant women or nursing mothers.
- 3.It is not for ophthalmic use.

#### WARNINGS:

#### General:

- If any irritation or other adverse reactions occurred, stop or reduce the drug, and consult a doctor.
- It should not be used for long, because it may induce tolerance to bacterium.
- 3. Keep out of reach of children.

#### Pregnancy and Nursing Mothers:

It is contraindicated in pregnant women or nursing mothers.

#### Children:

Children should use with cautions, and with the guard of adults.

#### Drug Interactions:

There is antagonism between ACNIL and erythromycin, so the combination of ACNIL and erythromycin is forbidden.

#### STORAGE:

Preserve in well closed container in a cool and dark place.

PACKAGE: 20ml/bottle, 30ml/bottle.

VALIDITY: 3 years

Mfg.by: Jiangsu Chenpai Bond Pharmaceutical Co., Ltd., Jiangsu Province, P.R. China

### Content of Labeling

#### **ACNIL**

acnil clindamycin hydrochloride and metronidazole liniment liniment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84277-5647	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

METRONIDAZOLE (UNII: 140QMO216E) (METRONIDAZOLE - UNII:140QMO216E)	METRONIDAZ OLE	8 mg in 30 mL
CLINDAMYCIN HYDROCHLORIDE (UNII: T200Q1YN1W) (CLINDAMYCIN - UNII: 3U02EL437C)	CLINDAMYCIN	10 mg in 30 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
2-(ETHYLTHIO)ETHANOL (UNII: 6091RQ1378)		
GLYCEROL FORMAL (UNII: 3L7GR2604E)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:84277- 5647-1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		05/01/2024		
		03/01/2024		

## Labeler - Jiangsu Chenpai Bond Pharmaceutical Co.,Ltd. (561021529)

## **Registrant -** Jiangsu Chenpai Bond Pharmaceutical Co.,Ltd. (561021529)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Jiangsu Chenpai Bond Pharmaceutical Co.,Ltd.		561021529	manufacture(84277-5647)	

Revised: 5/2024 Jiangsu Chenpai Bond Pharmaceutical Co.,Ltd.