# **UBREDOL-** methyl salicylate ointment Pharmadel LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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### **Ubredol Methyl Salicylate 10% (WP)**

#### **Drug Facts**

### Active ingredient & Purpose

Active ingredient	Purpose	
Methyl salicylate 10%	Topical analgesic	

#### Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

# Warnings

# For external use only. Avoid contact with the eyes.

#### Do not

- apply on wounds or irritated skin
- bandage tightly

# Stop use and ask doctor immediately if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

# If pregnant or breast-feeding,

ask a health care professional before use.

# Keep out of reach of children.

If swallowed get medical help, or contact a Poison Control Center immediately.

#### **Directions**

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: do not use, consult a doctor

#### Other information

- store between 59°- 86°F (15 30°C)
- do not use if clear seal over jar is broken, torn or missing

### Inactive ingredients

camphor, D&C yellow #11, eucalyptus oil, lanolin oil, levomenthol, mineral oil, petrolatum, propylparaben, tea tree oil

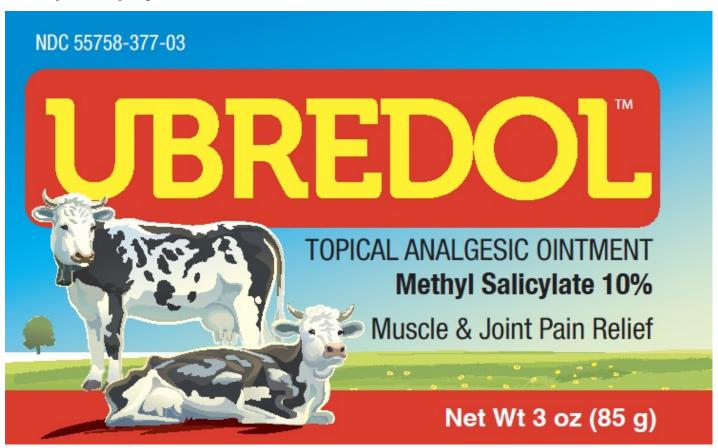
#### Distributed by:

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# **Principal Display Panel**



## **UBREDOL**

methyl salicylate ointment

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:55758-377

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) METHYL SALICYLATE 10 g in 100 g

## **Inactive Ingredients**

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Ingredient Name	Strength
CAMPHOR, (-)- (UNII: 213N3S8275)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: 1900E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN OIL (UNII: OVV5IIJ58F)	

Packaging				
# Item	n Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55	5758-377-	85 g in 1 JAR; Type 0: Not a Combination Product	06/20/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	06/20/2023		
	part348	06/20/2023		

# Labeler - Pharmadel LLC (030129680)

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