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.

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:

Pharmadel LLC

New Castle, DE 19720

+1-866-359-3478

Principal Display Panel

UBREDOL

methyl salicylate ointment

Product Information			
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	
Ingredient Name	**Strength**
CAMPHOR, (-)- (UNII: 213N3S8275)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
D&C YELLOW NO. 11 (UNII: 44F3HYL954)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN OIL (UNII: OVV5IIJ58F)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55758-377-03	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	

Labeler - Pharmadel LLC (030129680)

Revised: 6/2023 Pharmadel LLC