APEAZ ULTRA- camphor (synthetic), menthol, and methyl salicylate cream cream
Innovus Pharmaceuticals, Inc.

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.

Apeaz Ultra

Active ingredient

Camphor 4%

Menthol 7.5%

Methyl Salicylate 10%

Purpose

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.

Do not use
- on wounds or damaged, broken or irritated skin
- with a heating pad

When using this product
- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor
- condition worsens or symptoms persist for more than 7 days

- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

Keep out of reach of children

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

Directions

- use only as directed
- 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: ask a doctor

Other information

Store at 20° to 25°C (68° to 77°F)

Do not purchase if outer seal is broken

Inactive ingredients

carbomer, cetearyl alcohol, water, FD&C Blue no 1, FD&C Yellow no 5, glucosamine sulfate, glyceryl monostearate, methyl sulfonyl methane, methylparaben, mineral oil 90, PEG-100, propylparaben, polysorbate 60, stearyl alcohol, triethanolamine

APEAZ ULTRA

camphor (synthetic), menthol, and methyl salicylate cream cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57483-101
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.0 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.5 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 mg

METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57483-101-01	1 in 1 CARTON	02/05/2018	
1		56.7 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/05/2018	

Labeler - Innovus Pharmaceuticals, Inc. (962507187)

Registrant - Innovus Pharmaceuticals, Inc. (962507187)

Revised: 1/2023 Innovus Pharmaceuticals, Inc.