

BM NATURAL MULLEIN EAR- belladonna, calendula, echinacea, hydrastis, mullein oil, viola odorata solution/ drops

BM Private Limited

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

BM Natural Mullein Ear Drops

Ethanol 35%, Distilled water, Glycerin, Methyl paraben, Propyl paraben

Active ingredients (Ref. stand.) Each mL contains Belladonna D10 0.008mL (HPUS)
Calendula Ø 0.010mL (HPUS) Echinacea Ø 0.002mL (HPUS) Hydrastis D3 0.002mL (HPUS) Mullein oil Ø 0.28mL (HPUS) Viola odorata Ø 0.002mL (HPUS)

Indications: Help support to relieve the symptoms of otalgia and otorrhoea, for detail please read the enclosed package (Product information leaflet).

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How to use: Instill 4-5 drops twice a day.




Care & contra-indications: This is a homeopathic product, no contra-indications are established.

Precautions/storage: Keep away from children and store at cool and dry place.

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Entire package label

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85816-6015
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VIOLA ODORATA (UNII: AET12U8B74) (VIOLA ODORATA - UNII:AET12U8B74)	VIOLA ODORATA	1 [hp_X] in 1 mL
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	10 [hp_X] in 1 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 mL
VERBASCUM THAPSUS (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS	1 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	1 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.6 mg in 1 mL
METHYLPARABEN (UNII: A2I8C7HI9T)	1 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.27 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.38 mL in 1 mL
ALCOHOL (UNII: 3K9958V90M)	0.35 mL in 1 mL

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85816-6015-1	15 mL in 1 BOTTLE, DROPPER; Type 6: Drug/Biologic Combination	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved homeopathic		01/01/2015	
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Labeler - BM Private Limited (645599762)

Establishment

Name	Address	ID/FEI	Business Operations
BM Private Limited		645599762	manufacture(85816-6015)