

**ARNICA DE LA ABUELA- heterotheca inuloides cass, wintergreen, balsam of peru ointment
LABORATORIOS BREMER, S.A.**

Drug Facts

Gaultheria Procumbens (Wintergreen Oil) 0,05 Oz.

Myroxylon Pareirae (Balsam of Peru) 0,03 Oz

Heterotheca Inuloides Cass (Arnica Ext. Fluid) 0,02 Oz

Analgesic in the treatment of muscle pain

Dose and use way: Apply 2 or 3 times a day on the affected area

Contraindications: Hypersensitivity to the formula ingredients.

If the problem persists consult your doctor. Secondary reactions. In

case of skin irritations suspend this product use.

Warning: Arnica (Extract) can be toxic if ingested

Wintergreen Oil can be toxic if ingested

For external use only

Pregnancy or nursing baby: Yes, this product apply
on pregnancy and nursing women.

Caution: Keep out the reach of the children.

Indications: Analgesic in the treatment of muscle pain

Excipient (Petrolatum and Parafin) Q.S. 3.52 Oz



ARNICA DE LA ABUELA

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60854-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HETEROTHECA INULOIDES FLOWER (UNII: W9NZ9OZF68) (HETEROTHECA INULOIDES FLOWER - UNII:W9NZ9OZF68)	HETEROTHECA INULOIDES FLOWER	0.59 g in 104 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	1.48 g in 104 mL
BALSAM PERU (UNII: 8P5F881OCY) (BALSAM PERU - UNII:8P5F881OCY)	BALSAM PERU	0.88 g in 104 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60854-001-01	44 mL in 1 CAN; Type 0: Not a Combination Product	01/01/2016	
2	NDC:60854-001-02	31 mL in 1 CAN; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/01/2016	

Labeler - LABORATORIOS BREMER, S.A. (811585264)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS BREMER, S.A.		811585264	manufacture(60854-001)