

BRUISES GONE GEL- calendula officinalis, arnica montana, hypericum perforatum, symphytum officinale, bellis perennis, ledum palustre, sulphuricum acidum gel

MedCare Group LLC

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.

DRUG FACTS:

ACTIVE INGREDIENTS:

Calendula Officinalis 1X, Arnica Montana 1X, 30C, Hypericum Perforatum 1X, 30C, Symphytum Officinale 3X, Bellis perennis 12X, Ledum Palustre 12X, Sulphuricum Acidum 12X, Calcarea Fluorica 30X, Ferrum Phosphoricum 30X, Rhus Toxicodendron 30X, Ruta Graveolens 30X, Natrum Sulphuricum 30C.

INDICATIONS:

For temporary relief of bumps, bruises, abrasions, strains, sprains, fractures, stiffness, for all body injuries.

WARNINGS:

☐ **If pregnant or breast-feeding,** ☐ ask a health professional before use.

☐ **Keep out of reach of children.** ☐ If swallowed, get medical help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

☐ **For topical use only.** ☐

STORAGE:

Store in a cool, dry place.

DIRECTIONS:

Apply a small amount every 10 minutes for 3 doses immediately after injury, then 2 to 3 times daily.

INACTIVE INGREDIENTS:

Biosaccharide Gum-1, Carbomer, Ethanol, Glycerin, NaPCA, Purified Water, Sodium Hydroxymethylglycinate, Tromethamine.

KEEP OUT OF REACH OF CHILDREN:

☐ **Keep out of reach of children.** ☐ If swallowed, get medical help or contact a Poison Control Center right away.

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QUESTIONS:

Dist. By: MedCare Group

Boothwyn, PA 19060

302-260-3111

www.medcaregroups.com

PACKAGE DISPLAY LABEL:

MedCare

Bruises Gone Gel

HOMEOPATHIC

Net Wt. 2 oz

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LOT: XXXXXXXXXX



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INACTIVE INGREDIENTS:

Biosaccharide Gum-1 (natural moisturizer derived from sorbitol), Carbomer (polymer), Ethanol, Glycerin, NaPCA (natural hydration factor), Purified Water, Sodium Hydroxymethylglycinate (preservative derived from amino acid glycine), Tromethamine (amine based organic buffer).

BRUISES GONE GEL

calendula officinalis, arnica montana, hypericum perforatum, symphytum officinale, bellis perennis, ledum palustre, sulphuricum acidum gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54557-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	1 [hp_X] in 1 mL

HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	1 [hp_X] in 1 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	3 [hp_X] in 1 mL
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	12 [hp_X] in 1 mL
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	12 [hp_X] in 1 mL
SULFURIC ACID (UNII: O40UQP6WCF) (SULFURIC ACID - UNII:O40UQP6WCF)	SULFURIC ACID	12 [hp_X] in 1 mL
CALCIUM FLUORIDE (UNII: O3B55K4YKI) (FLUORIDE ION - UNII:Q80VPU408O)	CALCIUM FLUORIDE	30 [hp_X] in 1 mL
FERRUM PHOSPHORICUM (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERRUM PHOSPHORICUM	30 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	30 [hp_X] in 1 mL
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	30 [hp_X] in 1 mL
SODIUM SULFATE (UNII: 0YPR65R21J) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SODIUM SULFATE	30 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BIOSACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	
TROMETHAMINE (UNII: 023C2WHX2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54557-0002-1	60 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/08/2013	

Labeler - MedCare Group LLC (038668689)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(54557-0002) , api manufacture(54557-0002) , label(54557-0002) , pack(54557-0002)

Revised: 8/2013

MedCare Group LLC