

TRAUMA CREAM - hepar sulph. calc., hypericum, phosphorus, aconitum nap., arnica, belladonna, bellis, calendula, colchicum, ledum, millefolium, rhus toxicodendron, apis mel., chamomilla, echinacea, hamamelis, hydrastis, ruta, symphytum cream
Newton Laboratories, Inc.

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.

Trauma Cream

INDICATIONS & USAGE SECTION

Trauma Cream: Formulated for symptoms associated with injury, trauma or surgery such as pain, stiffness, swelling, bruising and inflammation.

DOSAGE & ADMINISTRATION SECTION

Directions: EXTERNAL USE ONLY. Ages 2 and up, apply a thin coating up to four times daily to affected area. Repeat as needed or as directed by your healthcare professional. Under age 2, consult a licensed healthcare professional. Avoid eye contact; if eye contact occurs, rinse with water for at least 15 minutes. If allergic response or irritation occurs or persists, discontinue use and consult a licensed healthcare professional.

OTC - ACTIVE INGREDIENT SECTION

Hepar sulph. calc. 10x, Hypericum 10x, Phosphorus 10x, Aconitum nap. 8x, Arnica 8x, Belladonna 8x, Bellis 8x, Calendula 8x, Colchicum 8x, Ledum 8x, Millefolium 8x, Rhus toxicodendron 8x, Apis mel. 3x, Arnica 3x, Calendula 3x, Chamomilla 3x, Echinacea 3x, Hamamelis 3x, Hydrastis 3x, Hypericum 3x, Ruta 3x, Symphytum 3x.

OTC - PURPOSE SECTION

Formulated for symptoms associated with injury, trauma or surgery such as pain, stiffness, swelling, bruising and inflammation.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water, Pomace Olive Oil, El Deodorized Cocoa Butter, Beeswax (organic), Jojoba Esters, Soy Lecithin (organic), USP Glycerin, natural (organic, vegetable), USP Gluten-free, non-GMO Cane Alcohol (organic), Grapefruit Seed Extract, Plant preservatives (natural), Gluten-free, non-GMO Xanthan Gum.

OTC - QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012 Questions?
1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children


PACKAGE LABEL

www.newtonlabs.net

Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, GA 30012

Questions? 1.800.448.7256

Warning: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.



NDC# 55714-2001-4

Trauma Cream

Formulated for symptoms associated with injury, trauma or surgery such as pain, stiffness, swelling, bruising and inflammation.

1.75 oz (50 g)

Directions: EXTERNAL USE ONLY. Ages 2 and up, apply a thin coating up to four times daily to affected area. Repeat as needed or as directed by your healthcare professional. Under age 2, consult a licensed healthcare professional. Avoid eye contact; if eye contact occurs, rinse with water for at least 15 minutes. If allergic response or irritation occurs or persists, discontinue use and consult a licensed healthcare professional.

Active Ingredients: Hepar sulph. calc. 10x, Hypericum 10x, Phosphorus 10x, Aconitum nap. 8x, Arnica 8x, Belladonna 8x, Bellis 8x, Calendula 8x, Colchicum 8x, Ledum 8x, Millefolium 8x, Rhus toxicodendron 8x, Apis mel. 3x, Arnica 3x, Calendula 3x, Chamomilla 3x, Echinacea 3x, Hamamelis 3x, Hydrastis 3x, Hypericum 3x, Ruta 3x, Symphytum 3x.

Inactive Ingredients: USP Purified water; Pomace olive oil; El deodorized cocoa butter; Beeswax (organic); Jojoba Esters; Soy lecithin (organic); USP Glycerin, natural (organic, vegetable); USP Gluten-free, non-GMO, cane alcohol (organic); Grapefruit seed extract; Plant preservatives (natural); Gluten-free, non-GMO, xanthan gum.

Stock# N222 Lot#

TRAUMA CREAM

hepar sulph. calc., hypericum, phosphorus, aconitum nap., arnica, belladonna, bellis, calendula, colchicum, ledum, millefolium, rhus toxicodendron, apis mel., chamomilla, echinacea, hamamelis, hydrastis, ruta, symphytum cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Calcium Sulfide (UNII: 1MBW07J51Q) (Calcium Sulfide - UNII:1MBW07J51Q)	Calcium Sulfide	10 [hp_X] in 1 g

Hypericum Perforatum (UNII: XK4IUX8MNB) (Hypericum Perforatum - UNII:XK4IUX8MNB)	Hypericum Perforatum	10 [hp_X] in 1 g
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	10 [hp_X] in 1 g
Aconitum Napellus (UNII: U0NQ8555JD) (Aconitum Napellus - UNII:U0NQ8555JD)	Aconitum Napellus	8 [hp_X] in 1 g
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	8 [hp_X] in 1 g
Atropa Belladonna (UNII: WQZ3G9PF0H) (Atropa Belladonna - UNII:WQZ3G9PF0H)	Atropa Belladonna	8 [hp_X] in 1 g
Bellis Perennis (UNII: 2HU33I03UY) (Bellis Perennis - UNII:2HU33I03UY)	Bellis Perennis	8 [hp_X] in 1 g
Calendula Officinalis Flowering Top (UNII: 18E7415PXQ) (Calendula Officinalis Flowering Top - UNII:18E7415PXQ)	Calendula Officinalis Flowering Top	8 [hp_X] in 1 g
Colchicum Autumnale Bulb (UNII: 993QHL78E6) (Colchicum Autumnale Bulb - UNII:993QHL78E6)	Colchicum Autumnale Bulb	8 [hp_X] in 1 g
Ledum Palustre Twig (UNII: 877L01IZ0P) (Ledum Palustre Twig - UNII:877L01IZ0P)	Ledum Palustre Twig	8 [hp_X] in 1 g
Achillea Millefolium (UNII: 2FXJ6SW4PK) (Achillea Millefolium - UNII:2FXJ6SW4PK)	Achillea Millefolium	8 [hp_X] in 1 g
Toxicodendron Pubescens Leaf (UNII: 6IO182RP7A) (Toxicodendron Pubescens Leaf - UNII:6IO182RP7A)	Toxicodendron Pubescens Leaf	8 [hp_X] in 1 g
Apis Mellifera (UNII: 7S82P3R43Z) (Apis Mellifera - UNII:7S82P3R43Z)	Apis Mellifera	3 [hp_X] in 1 g
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	3 [hp_X] in 1 g
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
Hamamelis Virginiana Root Bark/stem Bark (UNII: T7S323PKJS) (Hamamelis Virginiana Root Bark/stem Bark - UNII:T7S323PKJS)	Hamamelis Virginiana Root Bark/stem Bark	3 [hp_X] in 1 g
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	3 [hp_X] in 1 g
Ruta Graveolens Flowering Top (UNII: N94C2U587S) (Ruta Graveolens Flowering Top - UNII:N94C2U587S)	Ruta Graveolens Flowering Top	3 [hp_X] in 1 g
Comfrey Root (UNII: M9VVZ08EKQ) (Comfrey Root - UNII:M9VVZ08EKQ)	Comfrey Root	3 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Olive Oil (UNII: 6UYK2WIW1E)	
Cocoa Butter (UNII: 512OYT1CRR)	
Royal Jelly (UNII: L497I37F0C)	
Jojoba Oil (UNII: 724GKU717M)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Glycerin (UNII: PDC6A3C0OX)	
Alcohol (UNII: 3K9958V90M)	
Citrus Paradisi Seed (UNII: 12F08874Y7)	
Lonicera Japonica Flower (UNII: 4465L2WS4Y)	
Xanthan Gum (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:55714-2001-4	50 g in 1 BOTTLE, PUMP		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved homeopathic			06/11/2013	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment			
Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-2001)

Revised: 8/2013

Newton Laboratories, Inc.