

ACCIDENT - INJURY RESCUE- aconitum nap, arnica, bellis, calendula, echinacea, gelsemium, hamamelis, hypericum, ledum, phosphorus, rhus toxicodendron, ruta, staphysag., symphytum, hydrastis canadensis. liquid
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.

Accident 2380L

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

QUESTIONS

newtonlabs.net ~ Questions? 800-448-7256

Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30013

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

OTC - PURPOSE SECTION

Formulated for symptoms associated with trauma or medical procedures such as pain, emotional upset, bruising and inflammation.

WARNINGS SECTION

Warning:Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding**, ask a doctor before use.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Echinacea 6x, Hydrastis 6x, Hypericum 6x, Symphytum 6x, Aconitum nap. 15x, Arnica 15x, Bellis 15x, Calendula 15x, Echinacea 15x, Gelsemium 15x, Hamamelis 15x, Hypericum 15x, Ledum 15x, Phos. 15x, Rhus tox. 15x, Ruta 15x, Staphysag. 15x, Symphytum 15x,

INDICATIONS & USAGE SECTION

Accident - Injury Rescue Formulated for symptoms associated with trauma or medical procedures such as pain, emotional upset, bruising and inflammation.

PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256
 Newton Laboratories, Inc. FDA Est# 1051203 • Conyers, GA 30013
Label statements have not been reviewed by the FDA.

NEWTON homeopathics™
 Since 1987

NDC# 55714-2380-1

Accident ~ Injury Rescue

Formulated for symptoms associated with trauma or medical procedures such as pain, emotional upset, bruising and inflammation.

Directions: Ages 12 and up, take 6 drops by mouth (ages 0 to 11, give 3 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Echinacea 6x, Hydrastis 6x, Hypericum 6x, Symphytum 6x, Aconitum nap. 15x, Arnica 15x, Bellis 15x, Calendula 15x, Echinacea 15x, Gelsemium 15x, Hamamelis 15x, Hypericum 15x, Ledum 15x, Phos. 15x, Rhus tox. 15x, Ruta 15x, Staphysag. 15x, Symphytum 15x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# N034 Lot#

1 FL OZ (30 ML)

ACCIDENT - INJURY RESCUE

aconitum nap, arnica, bellis, calendula, echinacea, gelsemium, hamamelis, hypericum, ledum, phosphorus, rhus toxicodendron, ruta, staphysag., symphytum, hydrastis canadensis. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2380
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	15 [hp_X] in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 mL
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	15 [hp_X] in 1 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	15 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	HAMAMELIS VIRGINIANA	15 [hp_X]

(HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	ROOT BARK/STEM BARK	in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	15 [hp_X] in 1 mL
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 mL
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	15 [hp_X] in 1 mL
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	15 [hp_X] in 1 mL
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2380-0	0.5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/17/2018	08/01/2019
2	NDC:55714-2380-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/17/2018	
3	NDC:55714-2380-2	50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/17/2018	08/01/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/17/2018	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2380)