

TRAUMEEL- aconitum napellus, arnica montana root, atropa belladonna, bellis perennis, calendula officinalis flowering top, matricaria recutita, echinacea, unspecified, echinacea purpurea, hamamelis virginiana root bark/stem bark, calcium sulfide, hypericum perforatum, mercurius solubilis, achillea millefolium and comfrey root ointment
MediNatura 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.

Traumeel Ointment

ACTIVE INGREDIENTS

Active ingredients: Each 100 g contains:

*Aconitum napellus 1X 0.050g; *Arnica montana, radix 3X 1.50g; *Belladonna 1X 0.050g; *Bellis perennis MT 0.100g; *Calendula officinalis MT 0.450g; *Chamomilla MT 0.150g; *Echinacea MT 0.150g; *Echinacea purpurea MT 0.150g; *Hamamelis virginiana MT 0.450g; Hepar sulphuris calcareum 6X 0.025g; *Hypericum perforatum 6X 0.090g; Mercurius solubilis 6X 0.040g; *Millefolium MT 0.090g; *Symphytum officinale 4X 0.100g.

*Natural Ingredients

PURPOSE

Analgesic

Warning

Warnings: For external use only. Cetylstearyl alcohol may cause local skin reactions, i.e. contact dermatitis. Do not apply over large areas of the body. Do not apply over open wounds or broken skin. If symptoms persist or worsen, or if a rash develops, a physician should be consulted.

Do not use if known sensitivity to Traumeel® ointment or any of its ingredients exists.

Keep out of

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

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

Store at room temperature. Protect from light.

Please retain outer carton for full product instructions.

WARNING: This product can expose you to mercury, which is known to the State of California to cause birth defects or other reproductive harm.

For more information go to www.P65Warnings.ca.gov.

Directions

Directions: Adults and children 4 years and older: Apply generously to affected areas 2 to 3 times daily, or as directed by your health professional. Massage thoroughly into skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging. For children under 4, use as directed by your health professional.

INACTIVE INGREDIENTS

Inactive ingredients:

Paraffin, liquid, Cetostearyl alcohol (type A), emulsifying, Paraffin, white soft, Ethanol (96 per cent)

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

Indications

For the temporary relief of muscular pain from sports injuries, bruising.

<p>Made in Germany Manufactured for and Distributed by: MediNatura Inc. 10421 Research Rd. Albuquerque, NM 87123 www.MediNatura.com US</p> <p>Questions? Call weekdays 8am-4PM Mountain 1-844-MediNatura (1-844-633-4628) or email info@medinatura.com</p>	<p>Active ingredients: Each 100 g contains: *Aconitum napellus 1X 0.050g; *Amica montana, radix 3X 1.50g; *Belladonna 1X 0.050g; *Bellis perennis MT 0.100g; *Calendula officinalis MT 0.450g; *Chamomilla MT 0.150g; *Echinacea MT 0.150g; *Echinacea purpurea MT 0.150g; *Hamamelis virginiana MT 0.450g; Hepar sulphuris calcareum 6X 0.025g; *Hypericum perforatum 6X 0.090g; Mercurius solubilis 6X 0.040g; *Millefolium MT 0.090g; *Symphytum officinale 4X 0.100g. *Natural Ingredients</p> <p>Inactive ingredients: Cetylstearyl alcohol, Ethanol, Paraffin, Purified water, White petrolatum.</p> <p>Directions: Adults and children 4 years and older: Apply generously to affected areas 2 to 3 times daily, or as directed by your health professional. Massage thoroughly into skin. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging. For children under 4, use as directed by your health professional.</p> <p>X is a homeopathic dilution. For more information, see www.medinatura.com</p> <p>Claims based on homeopathic practice, not accepted medical evidence. Not FDA evaluated.</p>
<p> Analgesic MediNatura™</p>	<p>OINTMENT NDC 62795-9487-8</p> <hr style="border: 2px solid red;"/> <h1 style="text-align: center;">Traumeel®</h1> <hr style="border: 2px solid red;"/> <p>HOMEOPATHIC Net Wt. 3.53 oz. (100g)</p>
<p> Health Practitioner Product. For sale only in the office of a Health Professional.</p>	<p>Indications: For the temporary relief of muscular pain from sports injuries, bruising.</p> <p>Warnings: For external use only. Cetylstearyl alcohol may cause local skin reactions, i.e. contact dermatitis. Do not apply over large areas of the body. Do not apply over open wounds or broken skin. If symptoms persist or worsen, or if a rash develops, a physician should be consulted. Do not use if known sensitivity to Traumeel® ointment or any of its ingredients exists. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.</p> <p>Store at room temperature. Protect from light.</p> <p>Please retain outer carton for full product instructions.</p> <p> WARNING: This product can expose you to mercury, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov. 090727/5002</p> <div style="text-align: right;">  7 87647 85309 0 </div>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Lot / Exp. date:</p> <p> Analgesic MediNatura™</p>	<p>OINTMENT</p> <hr style="border: 2px solid red;"/> <h1 style="text-align: center;">Traumeel®</h1> <hr style="border: 2px solid red;"/> <p>HOMEOPATHIC Net Wt. 3.53 oz. (100g)</p>

Add image transcription here...

TRAUMEEL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62795-9487
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	1 [hp_X] in 1 g
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	3 [hp_X] in 1 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	1 [hp_X] in 1 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 1 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 g
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	1 [hp_X] in 1 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	1 [hp_X] in 1 g
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [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	1 [hp_X] in 1 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 g
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 1 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 1 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	4 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62795-9487-8	1 in 1 CARTON	12/14/2021	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

unapproved homeopathic		12/14/2021	
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Labeler - MediNatura Inc (079324099)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(62795-9487)

Revised: 9/2023

MediNatura Inc