

TRAUMEEL RX- traumeel rx tablet
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 Rx Tablet

INDICATIONS & USAGE SECTION

Traumeel[®] tablets are an analgesic / anti-inflammatory homeopathic drug product indicated for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.

Dosage

Adults and children 4 years and older: 1 tablets per day 3 times per day or as directed by a health practitioner.

For children under 4 years: As directed by a health practitioner.

Allow to completely dissolve in the mouth.

WARNINGS

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

Ingredients

Active Ingredients:

Ingredient name	Potency	Quantity	Final dilution
Aconitum napellus	3X		30 mg 4X
Arnica montana, radix	2X		15 mg 3.3X
Belladonna	4X		75 mg 4.6X
Bellis perennis	2X		6 mg 3.7X
Calendula officinalis	2X		15 mg 3.3X
Chamomilla	3X		24 mg 4.1X
Echinacea	2X		6 mg 3.7X
Echinacea purpurea	2X		6 mg 3.7X
Hamamelis virginiana	2X		15 mg 3.3X
Hepar sulphuris calcareum	8X		30 mg 9X
Hypericum perforatum	2X		3 mg 4X
Mercurius solubilis	8X		30 mg 9X
Millefolium	3X		15 mg 4.3X

Symphytum officinale

8X

24 mg 9.1X

INACTIVE INGREDIENT

Lactose 6.0 mg

Magnesium stearate 1.5 mg

Traumeel Rx Tablets



TRAUMEEL RX

traumeel rx tablet

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:50 114-9483

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	4 [hp_X]
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	2 [hp_X]
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	3 [hp_X]
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	2 [hp_X]
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	2 [hp_X]
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	2 [hp_X]
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	2 [hp_X]
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	8 [hp_X]
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	3 [hp_X]
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV) (HAMAMELIS VIRGINIANA LEAF - UNII:T07U1161SV)	HAMAMELIS VIRGINIANA LEAF	2 [hp_X]
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X]
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	8 [hp_X]
ACONITUM NAPELLUS ROOT (UNII: KPD2N7348X) (ACONITUM NAPELLUS ROOT - UNII:KPD2N7348X)	ACONITUM NAPELLUS ROOT	3 [hp_X]
SYMPHYTUM OFFICINALE WHOLE (UNII: H8FJJ6KX5Y) (SYMPHYTUM OFFICINALE WHOLE - UNII:H8FJJ6KX5Y)	SYMPHYTUM OFFICINALE WHOLE	8 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-9483-2	1 in 1 CARTON	07/01/2016	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50114-9483-3	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2016	

Labeler - MediNatura Inc (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(50114-9483)

Revised: 3/2019

MediNatura Inc