TRAUMEEL COMBO PACK - traumeel
Heel 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 Combo Pack

ACTIVE INGREDIENTS

Traumeel Tablet:

Each 300 mg tablet contains as active ingredients: Aconitum napellus 3X 30 mg; Arnica montana, radix 3X 40 mg; Belladonna 4X 75 mg; Bellis perennis 2X 6 mg; Calendula officinalis 2X 15 mg; Chamomilla 3X 24 mg; Echinacea 2X 6 mg; Echinacea purpurea 2X 6 mg; Hamamelis virginiana 2X 15 mg; Hepar sulphuris calcareum 8X 15 mg; Hypericum perforatum 3X 8 mg; Mercurius solubilis 8X 15 mg; Millefolium 3X 15 mg; Symphytum officinale 8X 24 mg.

Traumeel Ointment:

Each 50g of ointment contains: Calendula officinalis 1X, Hamamelis virginiana 1X, Arnica montana, radix 3X 0.75 g each; Aconitum napellus 3X, Belladonna 3X 0.5 g each; Bellis perennis 1X, Chamomilla 1X, Echinacea 1X, Echinacea purpurea 1X 0.25 g each; Millefolium 1X 0.15 g; Hepar sulphuris calcareum 8X 0.125 g; Mercurius solubilis 8X 0.06g; Symphytum officinale 4X 0.05 g Hypericum perforatum 6X 0.045 g.

PURPOSE

Traumeel Tablet:

Aconitum napellus 3X 30 mg.....Reduces pain after injury
Arnica montana, radix 3X 40 mg.....Reduces pain due to bruises
Belladonna 4X 75 mg.....Reduces pain
Bellis perennis 2X 6 mg.....Reduces pain due to bruises
Calendula officinalis 2X 15 mg.....Stimulates healing process
Chamomilla 3X 24 mg.....Soothing pain relief
Echinacea 2X 6 mg.....Immune support
Echinacea purpurea 2X 6 mg.....Stimulates healing process
Hamamelis virginiana 2X 15 mg.....Relieves bruised soreness
Hepar sulphuris calcareum 8X 15 mg....Stimulates injury healing
Hypericum perforatum 3X 8 mg.....Relieves pain
Mercurius solubilis 8X 15 mg.....Reduces joint pain
Millefolium 3X 15 mg.....Treats minor bleeding
Symphytum officinale 8X 24 mg.....Relieves joint pain

Traumeel Ointment:

Calendula officinalis 1X 1.5 g.....Stimulates healing process
Hamamelis virginiana 1X 1.5 g.....Relieves bruised soreness
Arnica montana, radix 3X 1.5 g.....Reduces bruising
Aconitum napellus 3X 1 g.....Reduces pain after injury

Belladonna 3X 1 g.....Reduces pain
Bellis perennis 1X 0.5 g.....Treats bruises
Chamomilla 1X 0.5 g.....Soothing pain relief
Echinacea 1X 0.5 g.....Immune support
Echinacea purpurea 1X 0.5 g.....Stimulates healing process
Millefolium 1X 0.3 g.....Treats minor bleeding
Hepar sulphuris calcareum 8X 0.25 g.....Stimulates injury healing
Mercurius solubilis 8X 0.12 g.....Reduces joint pain
Symphytum officinale 4X 0.1 g.....Relieves joint pain
Hypericum perforatum 6X 0.09 g.....Relieves pain

KEEP OUT OF REACH OF CHILDREN
Traumeel Tablets:

Keep this and all medicine out of the reach of children.

Traumeel Ointment:

Keep this and all medicine out of the reach of children.

INDICATIONS AND USAGE
Traumeel Tablets:

For the temporary relief of pain due to:

- Muscular pain
- Joint pain
- Sports injuries
- Bruising

Traumeel Ointment:

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

WARNINGS
Traumeel Tablets:

If symptoms persist or worsen, a physician should be consulted. If pregnant or breast-feeding, ask a health care professional before use.

Traumeel Ointment:

For external use only. 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. In rare cases, allergic skin reactions may develop. Do not use if known sensitivity to Traumeel or any of its ingredients exists.

DOSAGE AND ADMINISTRATION

Traumeel Tablets:

Adults and children above 6 years: 1 tablet 3 times daily or as directed by a physician. Infants and children to 6 years: 1/2 the adult dosage.
Place tablet under the tongue or in mouth and completely dissolve.

Traumeel Ointment:

Adults, children and infants: Apply generously to affected areas 2 to 3 times daily, or as needed. Rub gently into the skin. Traumeel may be applied using mild compression bandaging and/or occlusive bandaging.

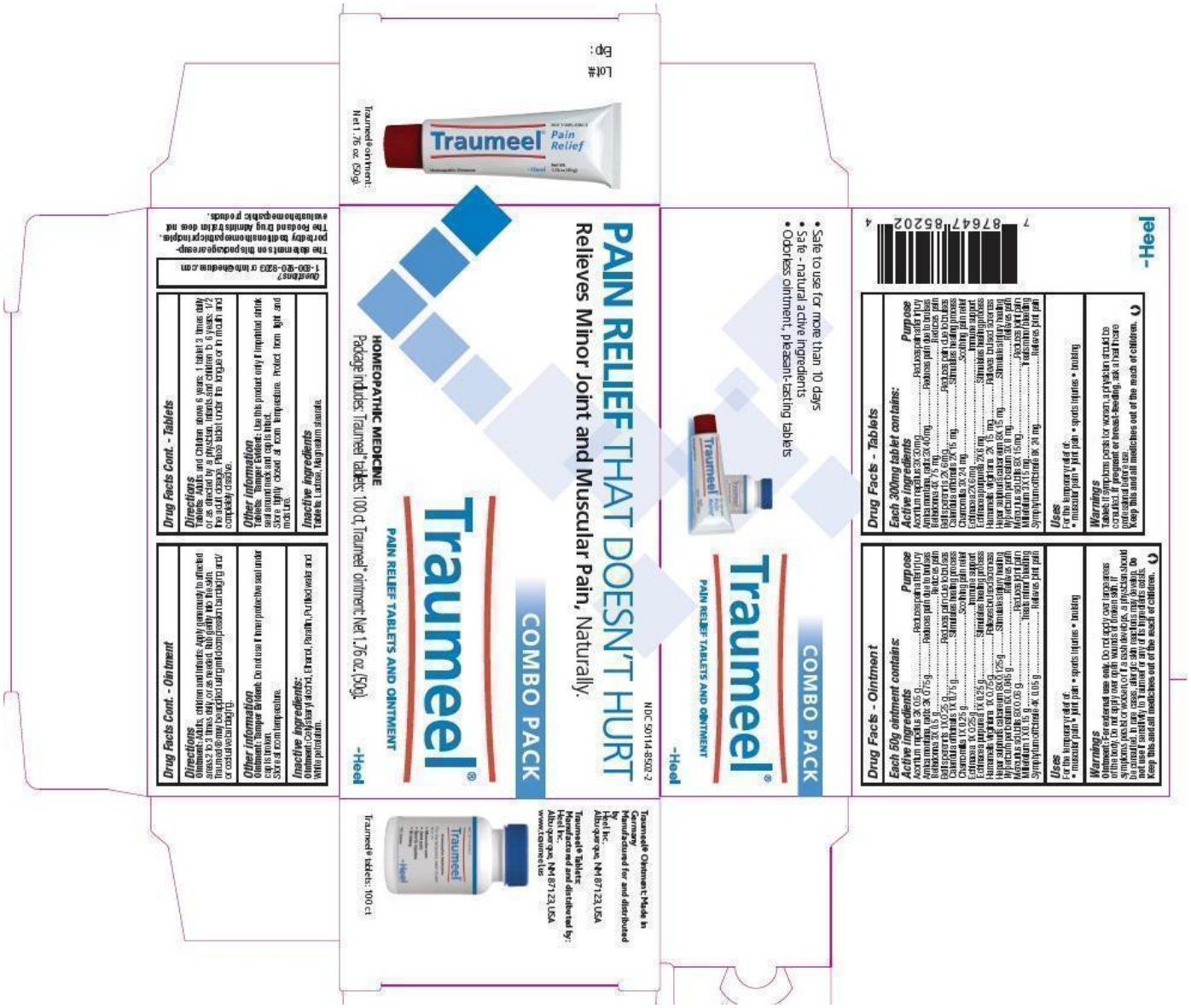
INACTIVE INGREDIENTS

Traumeel Tablets:

Lactose, Magnesium stearate

Traumeel Ointment:

Cetylstearyl alcohol, Ethanol, Parafin, Purified water, White petrolatum



TRAUMEEL COMBO PACK

traumeel kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50114-8502

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-8502-2	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	100
Part 2	1 TUBE	50 g

Part 1 of 2

TRAUMEEL

aconitum napellus and arnica montana root and atropa belladonna and bellis perennis and calendula officinalis flowering top and chamomile and echinacea, unspecified and echinacea purpurea and hamamelis virginiana root bark/stem bark and calcium sulfide and hypericum perforatum and mercurius solubilis and achillea millefolium and comfrey root tablet

Product Information

Item Code (Source)	NDC:50114-6150		
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X]
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	3 [hp_X]
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	4 [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]
CHAMOMILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	3 [hp_X]
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	2 [hp_X]
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	2 [hp_X]
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	2 [hp_X]
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	8 [hp_X]
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X]
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	8 [hp_X]
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	3 [hp_X]
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	8 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (Tablet)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	Heel
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-6150-2	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/1984	

Part 2 of 2

TRAUMEEL

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

Product Information

Item Code (Source)	NDC:51885-3302		
Route of Administration	TOPICAL	**DEA Schedule**	

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 100 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 100 g
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	3 [hp_X] in 100 g
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	3 [hp_X] in 100 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	3 [hp_X] in 100 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	1 [hp_X] in 100 g

MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	1 [hp_X] in 100 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	1 [hp_X] in 100 g
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	1 [hp_X] in 100 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	1 [hp_X] in 100 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	8 [hp_X] in 100 g
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	8 [hp_X] in 100 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	4 [hp_X] in 100 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51885-3302-3	1 in 1 CARTON		
1		50 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/31/1986	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/31/2012	

Labeler - Heel Inc (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Heel Inc		102783016	manufacture(50114-6150)

Establishment

Name	Address	ID/FEI	Business Operations
Biologische Heilmittel Heel		315635359	manufacture(51885-3302)