

**VALERIANAHEEL - valerian and trinitrophenol and prunus spinosa flower bud and hops and hypericum perforatum and melissa officinalis and avena sativa flowering top and matricaria recutita and ammonium bromide and potassium bromide and sodium bromide liquid
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.

Valerianaheel Oral Drop

KEEP OUT OF REACH OF CHILDREN

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

INDICATIONS AND USAGE

For the temporary relief of:

- Sleeplessness
- Restlessness
- Nervous tension and exhaustion

WARNINGS

If symptoms persist or worsen, a physician should be consulted. As with any drug, if you are pregnant or nursing a baby, seek the advise of a health care professional before using this product.

DOSAGE AND ADMINISTRATION

Adults and children above 11 years: 10 drops orally, 3 times daily, or as directed by a physician. Consult a physician for use in children under 12 years of age.

ACTIVE INGREDIENT

Each 50 ml contains as active ingredients: Valeriana officinalis 2X 32.5 ml; Picricum acidum 6X 5 ml; Prunus spinosa 2X 2.5 ml; Humulus lupulus 2X 2.5 ml; Hypericum perforatum 3X 2.5 ml; Melissa officinalis 2X 1.5 ml; Avena sativa 2X 1 ml; Chamomilla 2X 1 ml; Ammonium bromatum 2X 0.5 ml; Kali bromatum 2X 0.5 ml; Natrum bromatum 2X 0.5 ml.

INACTIVE INGREDIENT

Inactive ingredients: Ethanol, Purified Water USP.

PURPOSE

Sleeplessness, Restlessness, Nervous tension and exhaustion

Ingredients: Each 50 ml contains as active ingredients: Valeriana officinalis 2X 32.5 ml; Picricum acidum 6X 5 ml; Prunus spinosa 2X 2.5 ml; Humulus lupulus 2X 2.5 ml; Hypericum perforatum 3X 2.5 ml; Melissa officinalis 2X 1.5 ml; Avena sativa 2X 1 ml; Chamomilla 2X 1 ml; Ammonium bromatum 2X 0.5 ml; Kali bromatum 2X 0.5 ml; Natrum bromatum 2X 0.5 ml. Inactive ingredients: Ethanol, Purified water USP.
(1X=1:10 dilution, 2X=1:100, 3X=1:1000, etc.)

NDC 50114-1165-4

Valerianaheel

Homeopathic Medication

For the temporary relief of:

- Sleeplessness
- Restlessness
- Nervous tension and exhaustion

50 ml (1.6 fl. oz.) Oral Drops

Contains ethyl alcohol 60% by volume

Dosage: Adults and Children above 11 years: 10 drops orally 3 times daily, or as directed by a physician. Consult a physician for use in children under 12 years of age.

Tamper Evident: Do not use this product if the safety ring is broken away from the base of the bottle cap.

Warnings: If symptoms persist or worsen, a physician should be consulted. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health care professional before using this product. Store tightly closed at room temperature. Protect from light. **Keep this and all medications out of the reach of children.**

Manufactured and distributed by:
Heel Inc.
Albuquerque, New Mexico, USA
www.heelusa.com • info@heelusa.com
1.800.920.9203



Lot#:

Exp:

-Heel

VALERIANAHEEL

valerian and trinitrophenol and prunus spinosa flower bud and hops and hypericum perforatum and melissa officinalis and avena sativa flowering top and matricaria recutita and ammonium bromide and potassium bromide and sodium bromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 114-1165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	2 [hp_X] in 50 mL
TRINITROPHENOL (UNII: A49OS0F91S) (TRINITROPHENOL - UNII:A49OS0F91S)	TRINITROPHENOL	6 [hp_X] in 50 mL
PRUNUS SPINOSA FLOWER BUD (UNII: 53Y84VPS2W) (PRUNUS SPINOSA FLOWER BUD - UNII:53Y84VPS2W)	PRUNUS SPINOSA FLOWER BUD	2 [hp_X] in 50 mL
HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	2 [hp_X] in 50 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 50 mL
MELISSA OFFICINALIS (UNII: YF70189L0N) (MELISSA OFFICINALIS - UNII:YF70189L0N)	MELISSA OFFICINALIS	2 [hp_X] in 50 mL
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	2 [hp_X] in 50 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	2 [hp_X] in 50 mL

AMMONIUM BROMIDE (UNII: R0JB3224WS) (AMMONIUM BROMIDE - UNII:R0JB3224WS)	AMMONIUM BROMIDE	2 [hp_X] in 50 mL
POTASSIUM BROMIDE (UNII: OSD78555ZM) (BROMIDE ION - UNII:952902IX06, POTASSIUM CATION - UNII:295O53K152)	POTASSIUM BROMIDE	2 mm in 50 mL
SODIUM BROMIDE (UNII: LC1V549NOM) (SODIUM CATION - UNII:LYR4M0NH37, BROMIDE ION - UNII:952902IX06)	SODIUM BROMIDE	2 [hp_X] in 50 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-1165-4	50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/1986	

Labeler - Heel Inc (102783016)

Establishment

Name	Address	ID/FEI	Business Operations
Heel Inc		102783016	manufacture

Revised: 2/2012

Heel Inc