

**CALMS FORTE- avena sativa flowering top, tribasic calcium phosphate, matricaria recutita, ferrosiferic phosphate, hops, potassium phosphate, dibasic, magnesium phosphate, dibasic trihydrate, sodium phosphate, dibasic, heptahydrate, and passiflora incarnata flower tablet
Hyland's 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.

CALMS FORTÉ®

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avena Sativa 4X HPUS	stress, nervousness
Calcarea Phosphorica 3X HPUS	restlessness
Chamomilla 4X HPUS	nervous irritability
Ferrum Phosphoricum 3X HPUS	nervousness
Humulus Lupulus 4X HPUS	occasional sleeplessness
Kali Phosphoricum 3X HPUS	irritability
Magnesia Phosphorica 3X HPUS	mental anxiousness
Natrum Phosphoricum 3X HPUS	anxiousness
Passiflora 4X HPUS	restless sleep from exhaustion

"HPUS" indicates the active ingredients are in the official Homeopathic Pharmacopœia of the United States.

Uses

Temporarily relieves the symptoms of occasional sleeplessness and restlessness with accompanying stress, anxiousness, nervousness and irritability.

Warnings

As with any drug, ask a doctor before use if pregnant or breast-feeding.

Consult a physician if symptoms persist for more than 7 days.

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

In case of accidental overdose, contact a medical professional or Poison Control Center immediately.

Do not use if imprinted tamper band is broken or missing.

In case of emergency, contact a medical professional or Poison Control Center immediately. Hyland's may also be contacted for emergency information about our products 24 hours a day, 7 days per week at (800) 624-9659.

Directions

Adults & children 12 years and over: As a relaxant: swallow 1-2 caplets with water as needed three times daily. For occasional sleeplessness: 1-3 caplets 1/2 to 1 hour before retiring. Children 6-12 years: As a relaxant: swallow 1 caplet with water as needed three times daily. For occasional sleeplessness: 1-2 caplets 1/2 to 1 hour before retiring.

Inactive ingredients

Lactose, Magnesium Stearate, Microcrystalline Cellulose, Starch (Corn and Tapioca).

Questions or comments?

(800) 624-9659

PRINCIPAL DISPLAY PANEL - 32 Caplet Bottle Carton

NDC 54973-3274-1

HOMEOPATHIC

Natural

Relief

NON-HABIT

FORMING

SINCE 1903

Hyland's®

Calms Forté®

Sleep Aid

Relieves stress to help you sleep*

Safe & Effective Relief of:

Occasional Sleeplessness

Restless Sleep

Stress

32 Caplets | Actual Size 356 mg



CALMS FORTE

avena sativa flowering top, tribasic calcium phosphate, matricaria recutita, ferrosferric phosphate, hops, potassium phosphate, dibasic, magnesium phosphate, dibasic trihydrate, sodium phosphate, dibasic, heptahydrate, and passiflora incarnata flower tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54973-3274

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	4 [hp_X]
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (PHOSPHATE ION - UNII:NK08V8K8HR)	TRIBASIC CALCIUM PHOSPHATE	3 [hp_X]
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	4 [hp_X]
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	3 [hp_X]
HOPS (UNII: 01G73H6H83) (HOPS - UNII:01G73H6H83)	HOPS	4 [hp_X]
POTASSIUM PHOSPHATE, DIBASIC (UNII: C171S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	3 [hp_X]
MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE (UNII: HF539G9L3Q) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM PHOSPHATE, DIBASIC TRIHYDRATE	3 [hp_X]
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	3 [hp_X]
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z) (PASSIFLORA INCARNATA FLOWER - UNII:K8F3G29S6Z)	PASSIFLORA INCARNATA FLOWER	4 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM PALMITOSTEARATE (UNII: R4OXA9G5BV)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	HYL;CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3274-1	1 in 1 CARTON	04/29/2016	
1		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved homeopathic		04/29/2016	
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Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3274) , pack(54973-3274) , label(54973-3274)

Revised: 12/2022

Hyland's Inc.