

**CALMS FORTE- avena sativa flowering top, tribasic calcium phosphate, matricaria recutita, ferrosiferrous 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 Forte

Drug Facts

Active ingredients	Purpose
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 symptoms of occasional sleeplessness or restlessness with accompanying stress, anxiousness, nervousness or irritability

Warnings

Stop use and ask a doctor if

Symptoms persist more than 7 days or worsen.

If pregnant or breastfeeding

Ask a health professional before use.

Keep out of reach of children

Directions

■ Use as directed.

Adults and children 12 years and over	As a relaxant: swallow 1-2 tablets with water until relieved, up to 3 times per day. For occasional sleeplessness: 1-3 tablets before bedtime.
Children 6 years to under 12 years	As a relaxant: swallow 1 tablet with water until relieved, up to 3 times per day. For occasional sleeplessness: 1-2 tablets before bedtime.

Inactive ingredients

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

Questions?

www.hylands.com or (800) 624-9659

***CLAIMS BASED ON TRADITIONAL HOMEOPATHIC PRACTICE, NOT ACCEPTED MEDICAL EVIDENCE. NOT FDA EVALUATED.**

DO NOT USE IF TAMPER-EVIDENT SEAL IS BROKEN OR MISSING.

PRINCIPAL DISPLAY PANEL - 50 TABLET BOTTLE CARTON

Hyland's

NATURALS™

CALMS

FORTE®

SLEEP AID*

Sleeplessness

Restless Sleep

Stress

Non-Habit

Forming

50

TABLETS

HOMEOPATHIC



PRINCIPAL DISPLAY PANEL - 100 TABLET BOTTLE CARTON



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:54973-3257
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: CI71S98N1Z) (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: O8232NY3S)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	HYL;CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3257-1	1 in 1 CARTON	04/29/2016	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3257-2	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2016	
3	NDC:54973-3257-3	4 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/29/2016	
4	NDC:54973-3257-7	1 in 1 CARTON	04/29/2016	
4		100 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(54973-3257) , pack(54973-3257) , label(54973-3257)

Revised: 12/2024

Hyland's Inc.