

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 Hyland's

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.

HYLAND'S 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 or worsen.

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

In case of emergency or accidental overdose, 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 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.

Other information

- Other information Do not use if imprinted "SEALED FOR YOUR PROTECTION" tamper-evident

bottle cap band is broken or missing.

Inactive ingredients

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

Questions or comments?

(800) 624-9659

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

PRINCIPAL DISPLAY PANEL - 50 Tablet Bottle Carton

NDC 54973-3257-1

HOMEOPATHIC

NON-HABIT

FORMING

Natural

Relief

SINCE 1903

Hyland's

**Calms Forté[®]
Sleep Aid**

Relieves stress to help you sleep*

Relief of:

Occasional Sleeplessness

Restless Sleep

Stress

50 Tablets | Actual Size 259 mg

***SEE NOTE ON BACK PANEL BELOW DRUG FACTS**



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
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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]
FERROSO FERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSO FERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSO FERRIC 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 PALMITO STEARATE (UNII: R4OXA9G5BV)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/29/2016	

Labeler - Hyland's (028570695)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3257) , pack(54973-3257)

Revised: 12/2019

Hyland's