

**AWAKEN- daphne mezereum bark,sulfur,delphinium staphisagria seed,sepia officinalis juice,sodium chloride,phosphoric acid,dibasic potassium phosphate and thuja occidentalis leafy twig 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.

Awaken

Natural relief of fatigue, drowsiness and irritability

Drug Facts

Active Ingredients	Purpose
Kali Phosphoricum 6X HPUS	difficulty waking, fatigue, anxiousness
Mezereum 12X HPUS	drowsiness
Natrum Muriaticum 6X HPUS	irritability, fatigue, drowsiness
Phosphoricum Acidum 6X HPUS	irritability, worry
Sepia 30X HPUS	drowsiness
Staphysagria 30X HPUS	irritability, drowsiness
Sulphur 12X HPUS	irritability, drowsiness
Thuja Occidentalis 30X HPUS	drowsiness, irritability

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

Uses

Temporarily relieves the symptoms of difficulty waking, fatigue, anxiousness, drowsiness, irritability and worry.

As with any drug, ask doctor before use if pregnant or breast-feeding. Do not use □ • more than directed □ • if you have a known allergy to any ingredient in this product.

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

Keep this and all medications out of 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: dissolve 1-2 tablets under tongue 3 times per day.

Acacia Gum, Lactose.

Questions or comments?

(800) 624-9659

PRINCIPAL DISPLAY PANEL - 50 TABLETS BOTTLE CARTON

Non-habit forming

NDC 54973-3333-1

HOMEOPATHIC

SINCE 1903

Hyland's®

Awaken

Natural relief of fatigue,
drowsiness and irritability*

50 QUICK-DISSOLVING TABLETS

ACTUAL SIZE 194 MG



AWAKEN

daphne mezereum bark,sulfur,delphinium staphisagria seed,sepia officinalis juice,sodium chloride,phosphoric acid,dibasic potassium phosphate and thuja occidentalis leafy twig tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54973-3333
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	30 [hp_X]
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X]
PHOSPHORIC ACID (UNII: E4GA8884NN) (PHOSPHORIC ACID - UNII:E4GA8884NN)	PHOSPHORIC ACID	6 [hp_X]
DIBASIC POTASSIUM PHOSPHATE (UNII: C17160N173) (POTASSIUM CATION	DIBASIC POTASSIUM	

DIBASIC POTASSIUM PHOSPHATE (UNII: C171S98N1Z) (POTASSIUM CATION - UNII:295O53K152)	DIBASIC POTASSIUM PHOSPHATE	6 [hp_X]
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	30 [hp_X]
SEPIA OFFICINALIS JUICE (UNII: QDL83WN8C2) (SEPIA OFFICINALIS JUICE - UNII:QDL83WN8C2)	SEPIA OFFICINALIS JUICE	30 [hp_X]
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	6 [hp_X]
DAPHNE MEZEREUM BARK (UNII: X2N6E405GV) (DAPHNE MEZEREUM BARK - UNII:X2N6E405GV)	DAPHNE MEZEREUM BARK	12 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
ACACIA (UNII: 5C5403N26O)	

Product Characteristics

Color	white (Off-White to White)	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3333-1	1 in 1 CARTON	12/01/2017	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3333-2	4 in 1 POUCH; Type 0: Not a Combination Product	12/01/2017	12/20/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/01/2017	

Labeler - Hyland's Inc. (008316655)

Establishment

Name	Address	ID/FEI	Business Operations
Hyland's Inc.		008316655	manufacture(54973-3333) , pack(54973-3333) , label(54973-3333)