

BABY CALMING- matricaria recutita, arabica coffee bean, strychnos ignatii seed, lycopodium clavatum spore, sodium chloride, platinum, anemone pulsatilla, and sulfur 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 Naturals Baby Calming

Drug Facts

Drug Facts

Active ingredients	Purpose
Chamomilla 6X HPUS	occasional sleeplessness, fussiness, and agitation
Coffea Cruda 6X HPUS	irritability
Ignatia Amara 30X HPUS (less than 0.0000000000001% Alkaloids, calculated)	restless sleep
Lycopodium 30X HPUS	unpredictable, irregular sleep
Natrum Muriaticum 6X HPUS	crying, irritability
Platinum Metallicum 30X HPUS	causeless crying, waking at night
Pulsatilla 6X HPUS	cries easily, inconsolable
Sulphur 12X HPUS	crying, restlessness, irritability

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

Uses

- Temporarily relieves symptoms of irritability or restlessness in children, including:
 - occasional sleeplessness ■ fussiness ■ agitation
 - restless sleep ■ unpredictable or irregular sleep ■ waking at night
 - crying ■ inconsolable behavior

Warnings

Stop use and ask a doctor if: ■ symptoms persist for more than 72 hours or worsen.

- symptoms are accompanied by a fever.

Keep out of reach of children.

Directions

■ Use as directed.

Children under 6 months	Ask a doctor before use.
Children 6 months to under 1 year	At onset of symptoms, dissolve 2 tablets on tongue every hour up to 4 hours. If symptoms persist, 2 tablets every 4 hours until relieved.
Children 1 year to under 3 years	At onset of symptoms, dissolve 3 tablets on tongue every hour up to 4 hours. If symptoms persist, 3 tablets every 4 hours until relieved.

Inactive ingredients

Acacia Gum, Lactose.

Questions or comments?

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.

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

Hyland's

Naturals™

•baby•

Calming

Tablets*

NO ARTIFICIAL FLAVORS,

DYES or PARABENS

Sleeplessness

Fussiness

Irritability

6+ MONTHS

125

QUICK-DISSOLVING TABLETS

HOMEOPATHIC



BABY CALMING

matricaria recutita, arabica coffee bean, strychnos ignatii seed, lycopodium clavatum spore, sodium chloride, platinum, anemone pulsatilla, and sulfur tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54973-3308

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_X]
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	6 [hp_X]
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	30 [hp_X]
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	30 [hp_X]
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	6 [hp_X]
PLATINUM (UNII: 49DFR088MY) (PLATINUM - UNII:49DFR088MY)	PLATINUM	30 [hp_X]
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	6 [hp_X]
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54973-3308-1	1 in 1 CARTON	01/20/2017	
1		125 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:54973-3308-2	6 in 1 PACKET; Type 0: Not a Combination Product	01/20/2017	12/20/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/20/2017	

Labeler - Hyland's (028570695)**Establishment**

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		008316655	manufacture(54973-3308) , pack(54973-3308) , label(54973-3308)

Establishment

Name	Address	ID/FEI	Business Operations
MeriCal, Inc.		029644978	manufacture(54973-3308)

Establishment

Name	Address	ID/FEI	Business Operations
Standard Homeopathic Company		080253323	manufacture(54973-3308) , pack(54973-3308) , label(54973-3308)

Revised: 12/2021

Hyland's