

B-SERENE RX- pyridoxine hydrochloride, cyanocobalamin, folic acid, and ginger patch
Spring Hill Therapeutics LLC

B-Serene^{Rx}

Supplement Facts		
Active Ingredients		
Serving Size: 1 patch	Amount per serving	% DV
Vitamin B6 (Pyridoxine Hydrochloride)	75 mg	3000%
Vitamin B12 (Cyanocobalamin)	12 mcg	150%
Folic Acid	1.2 mg	150%
Ginger	500 mg	*

Daily Value for adults and children four or more years of age

* Daily Value (DV) not established

Uses

B-Serene Rx is indicated to provide B-Vitamin supplementation, with ginger to help calm pregnancy related nausea and vomiting (morning sickness), and may be used in conjunction with a physician prescribed prenatal regimen.

Warnings

For external use only • Use only as directed • Avoid contact with eyes and mucous membranes • Do not use with heating devices or pads • Do not bandage tightly • If contact does occur with eyes rinse with cold water and call a doctor • Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. While prescribing this nutritional supplement for pregnant women, nursing mothers or for women prior to conception, their medical condition and any drugs, herbs and/or supplements consumption should be considered. • Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. Concomitant use of ginger in patients with heavy bleeding disorders, or who are on anti-coagulant or anti-platelet therapy, may increase the risk of bleeding.

Inactive Ingredients

Methacrylic acid, ethylhexylacrylate, bentonite, sodium stearate.

Do not use

On wounds or damaged skin. Children under 12 years old, consult a doctor. If you are allergic to any ingredients in this product. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Keep out of the reach of children.

Directions

Use one patch as directed or every 6-12 hours.

Other Information

Store at 25°C (77°F) excursions permitted to 15°-30°C (59°-86° F)

See USP Controlled Room Temperature • Protect from freezing.

These statements have not been approved by the FDA, This product is not intended to diagnose, treat, cure or prevent any disease.

SPRING HILL THERAPEUTICS

8270 Woodland Center Blvd. • Tampa, FL 33614
FOR QUESTIONS CALL 813-388-8735

PRINCIPAL DISPLAY PANEL - 30 Patch Bag Label

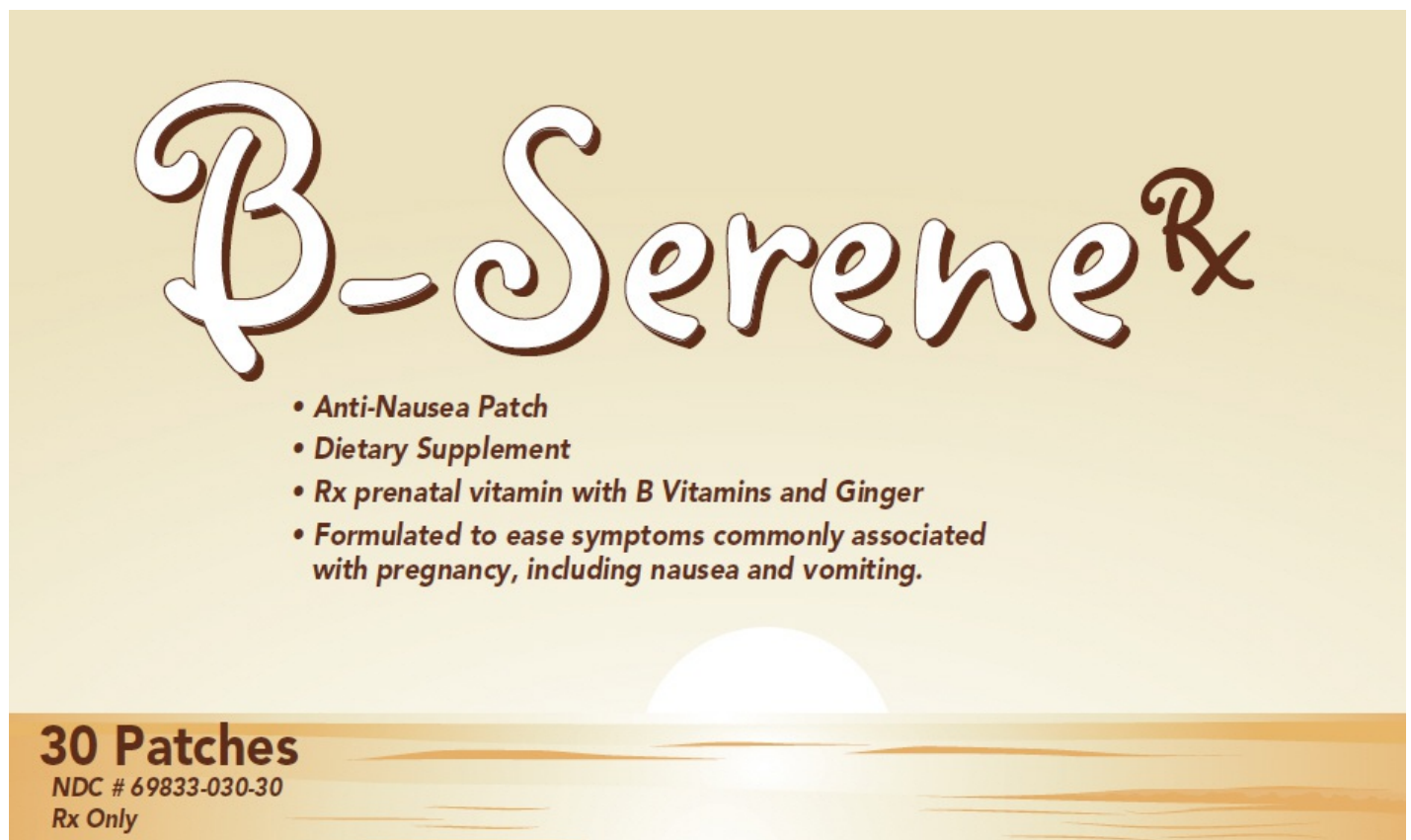
B-Serene^{Rx}

- *Anti-Nausea Patch*
- *Dietary Supplement*
- *Rx prenatal vitamin with B Vitamins and Ginger*
- *Formulated to ease symptoms commonly associated with pregnancy, including nausea and vomiting.*

30 Patches

NDC # 69833-030-30

Rx Only



B-SERENE RX

pyridoxine hydrochloride, cyanocobalamin, folic acid, and ginger patch

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69833-030
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	75 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1200 ug
Ginger (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	500 mg

Inactive Ingredients

Ingredient Name	Strength
2-Ethylhexyl Acrylate (UNII: HR49R9S6XG)	
Methacrylic Acid (UNII: 1CS02G8656)	
Bentonite (UNII: A3N5ZCN45C)	
Sodium Stearate (UNII: QU7E2XA9TG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69833-030-30	30 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/05/2015	

Labeler - Spring Hill Therapeutics LLC (079813250)

Revised: 1/2016

Spring Hill Therapeutics LLC