

RELAX AM-PM- valerian root, passiflora, magnesium carbonate tablet
Foster Regal Laboratories

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.

Relax AM-PM

EACH TABLET CONTAINS:

6 parts Valerian Root (Quad-Strength) 1X, 3 parts Passiflora (Quad-Strength) 1X, 1 part Magnesium Carbonate 1X.

For Relief of Muscle Spasms
Tension and Stress

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. In case of accidental overdose seek professional assistance or contact a poison control center immediately.

INDICATIONS: For temporary relief of muscle spasms, tension and stress.

Warning: Do not give to children under twelve except under the advice and supervision of a doctor. If you are pregnant or nursing a baby seek the advice of a health professional before using this product. Do not exceed recommended dosage. Consult a doctor if symptoms are more than mild or if they persist.

Directions: Adults and children 12 or more years of age.

Muscle Spasms - Take 1 or 2 tablets every 3 hours, until relief is obtained. To help prevent recurrence of muscle spasms, continue to take 1 or 2 tablets every 4 hours as needed.

Tension and Stress - Take 1 or 2 tablets every 4 hours, preferably with meals and at bedtime. To help prevent tension and stress take 1 or 2 tablets every 4 hours as needed.

Dosage should not exceed 12 tablets in any 24 hour period.

Lactose Monohydrate, Maltodextrin, Sodium Starch Glycolate Type A Potato, Stearic Acid, Silica

Relax AM-PM[®] is made from natural ingredients and may have a distinctive odor.
TAMPER EVIDENT: Do not use this product if imprinted foil seal under cap is broken or missing.
WARNINGS: Do not give to children under twelve except under the advice and supervision of a doctor. If you are pregnant or nursing a baby seek the advice of a health professional before using this product. Do not exceed recommended dosage. Consult your doctor if symptoms are more than mild or if they persist.
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
In case of accidental overdose seek professional assistance or contact a poison control center immediately.

NDC 64175-991-90

FOSTER REGAL[®]
The Best Choice.[®]
Relax AM-PM[®]

Natural Relaxant

For Relief of Muscle Spasms
Tension and Stress

Homeopathic

90 TABLETS

INDICATIONS: For temporary relief of muscle spasms, tension and stress.
DIRECTIONS: Adults and children 12 or more years of age:
MUSCLE SPASMS-Take 1 or 2 tablets every 3 hours, until relief is obtained. To help prevent recurrence of muscle spasms, continue to take 1 or 2 tablets every 4 hours as needed.
TENSION AND STRESS-Take 1 or 2 tablets every 4 hours, preferably with meals and at bedtime. To help prevent tension and stress take 1 or 2 tablets every 4 hours as needed.
Dosage should not exceed 12 tablets in any 24 hour period.
EACH TABLET CONTAINS: 6 parts Valerian Root (Quad Strength) 1X, 3 parts Passiflora (Quad Strength) 1X, 1 part Magnesium Carbonate 1X.
Keep tightly closed. Store at room temperature: 59°-86° F (15° to 30° C).
Mfg. for: **FOSTER REGAL Laboratories[®]**
115 S.C.T. Ct., White House, TN 37188, Made in U.S.A.

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RELAX AM-PM

valerian root, passiflora, magnesium carbonate tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64175-991

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	6 [hp_X]
PASSIFLORA INCARNATA FLOWER (UNII: K8F3G29S6Z) (PASSIFLORA INCARNATA FLOWER - UNII:K8F3G29S6Z)	PASSIFLORA INCARNATA FLOWER	3 [hp_X]
MAGNESIUM CARBONATE (UNII: 0E53J927NA) (CARBONATE ION - UNII:7UJQ5OPE7D)	MAGNESIUM CARBONATE	1 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	brown (brown with dark brown speckels)	Score	no score
Shape	ROUND (Tablet)	Size	11mm
Flavor		Imprint Code	36
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64175-991-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2011	
2	NDC:64175-991-45	45 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2011	
3	NDC:64175-991-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/16/2011	

Labeler - Foster Regal Laboratories (807396481)

Registrant - Dee Cee Laboratories (034731893)