

**MENOPAUSE HF- cimicifuga racemosa, trifolium pratense, magnesia carbonica, agnus castus 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.*

-----

**Menopause-HF**

Cimicifuga racemosa 1X HPUS

Trifolium pratense 1X HPUS

Magnesia carbonica 1X HPUS

Agnus castus 1X HPUS

Relieves hot flashes and mood changes

Supportive phytoestrogens, isoflavones for other ingredients

Relieves cramps, nervousness, and muscle spasms

Improves melancholy and perimenopausal hormone imbalance

**Keep out of reach of children**

**Uses:**Relieves hot flashes, mood changes associated with perimenopausal hormone changes.

**Warnings**

Allergy Alert: Rare allergic reaction to Red clover (Trifolium pratense): includes skin reactions; to Black Cohosh (Cimicifuga racemosa): includes stomach discomfort.

**Directions:**

Adults take 1 or 2 tablets 3 times daily with meals. An extra dose may be taken at bedtime if needed. Do not exceed 10 tablets in a 24 hour period. The smallest effective dose should be used. Do not give to children under 12. Do not exceed recommended dose.

**Other Information:**

B-complex vitamins are complementary when used within the same day as this drug. 1X indicates a 1:9 homeopathic diluted ingredient. The letters HPUS indicate that these ingredients are officially included in the Homeopathic Pharmacopeia of the United States. Store at controlled room temperature 59-86F (15-30 C) Do not use if imprinted safety seal under cap is broken or missing.

Inactive ingredients: Lactose, vegetable stearic acid, vegetable cellulose, vegetable magnesium stearate.

NDC 64175-525-90

**FOSTER REGAL**<sup>®</sup>The Best Choice.<sup>®</sup>**Menopause-HF**<sup>™</sup>  
Homeopathic FormulaGluten Free **Soy Free**  
**Non-GMO**Relieves Hot Flashes  
and Mood Changes  
Associated with Menopause**90 TABLETS****Drug Facts****Active Ingredients: (in each tablet) Purpose**Cimicifuga racemosa 1X HPUS Relieves hot flashes and mood changes  
Trifolium pratense 1X HPUS Supportive phytoestrogens, isoflavones for other ingredients

Magnesia carbonica 1X HPUS Relieves cramps, nervousness and muscle spasms

Agnus castus 1X HPUS Improves melancholy and perimenopausal hormone imbalance

**Uses** • Relieves hot flashes, mood changes associated with perimenopausal hormone changes.**Warnings**Allergy Alert: Rare allergic reaction to Red clover (Trifolium pratense); includes skin reactions; to Black cohosh (Cimicifuga racemosa); includes stomach discomfort.  
**Keep out of reach of children.****Do not use** • if you are taking hormone replacement therapy or are pregnant or breast feeding.**Stop use and ask a doctor if** • symptoms persist or worsen.**Directions**

• Adults take 1 or 2 tablets 3 times daily with meals. An extra dose may be taken at bedtime if needed. Do not exceed 10 tablets in a 24 hour period. The smallest effective dose should be used. Do not give to children under 12. Do not exceed recommended dose.

**Other Information**

• B-complex vitamins are complementary when used within the same day as this drug. • 1X indicates a 1:9 homeopathic diluted ingredient. The letters HPUS indicate that these ingredients are officially included in the Homeopathic Pharmacopoeia of the United States. • Store at controlled room temperature 59-86°F (15°-30° C) • Do not use if imprinted safety seal under cap is broken or missing.

**Inactive Ingredients:** Lactose, vegetable stearic acid, vegetable cellulose, vegetable magnesium stearate.Mfg. by: **Foster Regal Laboratories**<sup>®</sup> Made in USA  
115 S.C.T. Ct., White House, TN 37188 64175

3 64175 52590 5

**MENOPAUSE HF**

cimicifuga racemosa, trifolium pratense, magnesia carbonica, agnus castus tablet

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:64175-525 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength   | Strength |
|---|---------------------|----------|
| <b>Black Cohosh</b> (UNII: K73E24S6X9) (Black Cohosh - UNII:K73E24S6X9)     | Black Cohosh        | 1 [hp_X] |
| <b>Red Clover</b> (UNII: L9153EKV2Y) (Red Clover - UNII:L9153EKV2Y)         | Red Clover          | 1 [hp_X] |
| <b>Magnesium Carbonate</b> (UNII: 0E53J927NA) (Magnesium - UNII:I38ZP9992A) | Magnesium Carbonate | 1 [hp_X] |
| <b>Chaste Tree</b> (UNII: 433OSF3U8A) (Chaste Tree - UNII:433OSF3U8A)       | Chaste Tree         | 1 [hp_X] |

**Inactive Ingredients**

| Ingredient Name                              | Strength |
|--|----------|
| <b>Lactose</b> (UNII: J2B2A4N98G)            |          |
| <b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M) |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30) |          |

**Product Characteristics**

| Color  | Score        |
|--|--------------|
| brown (Light brown with dark brown speckles) | no score     |
| Shape  | Size         |
| ROUND (Tablet)                               | 11mm         |
| Flavor                                       | Imprint Code |
|  | M            |
| Contains                                     |              |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:64175-525-90 | 90 in 1 BOTTLE      |                      |                    |

## Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic |  | 08/01/2010           |                    |

**Labeler** - Foster Regal Laboratories (807396481)

**Registrant** - Dee Cee Laboratories (034731893)

## Establishment

| Name                 | Address | ID/FEI    | Business Operations |
|----------------------|---------|-----------|---------------------|
| Dee Cee Laboratories |         | 034731893 | manufacture         |

Revised: 1/2012

Foster Regal Laboratories