CAPMIST DM- dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride tablet
Capital Pharmaceutical

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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CAPMIST DM TABLETS

Drug Facts
Active ingredients
(in each tablet)
Dextromethorphan HBr 30 mg
Guaifenesin 400 mg
Pseudoephedrine HCl 30 mg

Purpose
Cough Suppressant
Expectorant
Nasal Decongestant

Description
Capmist DM is a green, oblong, capsule shaped, scored tablet, imprinted CAP DM on one side and blank on the other.

Uses
Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passages

Warnings
Do not exceed recommended dosage.

Do not use this product
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have
- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
• high blood pressure
• thyroid disease
• diabetes
• trouble urinating due to enlargement of the prostate gland

Stop use and ask a doctor if
• nervousness, dizziness, or sleeplessness occur
• cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
• new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.
In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
Do not exceed recommended dosage.

| Adults and children 12 years of age and over: | 1 tablet every 6 hours, not to exceed 4 tablets in 24 hours. |
| Children 12 years of age and younger: | Consult a doctor. |

Other information
Store at 15° - 30°C (59° - 86°F).

Capmist DM is a light green, oblong, capsule shaped, scored tablet, debossed "CAP" bisect "DM" on one side and blank on the other.

Contains color additives including FD&C Yellow No. 5 (tartrazine).

Supplied in a tight, light-resistant container with a child-resistant cap.

Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #1 aluminum lake, FD&C Yellow #5 aluminum lake, hypromellose, maltodextrin, povidone, slicified microcrystalline cellulose, and stearic acid.

Questions? Comments?
Serious side effects may be reported to this
Product Packaging
The packaging below represents the labeling currently used:

Principal display panel and side panel for 90 tablets labeling:

NDC 29978-606-90

CAPMIST DM
TABLETS

COUGH SUPPRESSANT · EXPECTORANT
NASAL DECONGESTANT

Each tablet contains:
Dextromethorphan HBr..............................30 mg
Guaifenesin........................................400 mg
Pseudoephedrine HCl............................30 mg

CAPITAL pharmaceutical 90 tablets

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Distributed by: Capital Pharma, Powell, OH 43065
1 (614) 638-4622 Rev. 02/12
CAPMIST DM

Drug Facts

Active ingredients
(in each tablet)
- Dextromethorphan HBr 30 mg .......... Cough Suppressant
- Guaifenesin 400 mg ...................... Expectorant
- Pseudoephedrine HCl 30 mg .......... Nasal Decongestant

Uses
Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:
- Cough due to minor throat and bronchial irritation
- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- Nasal congestion
- Reduces swelling of nasal passages

Warnings
Do not exceed recommended dosage.
Do not use this product
- If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have:
- A cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- A cough that occurs with too much phlegm (mucus)
- Heart disease
- High blood pressure
- Diabetes
- Trouble urinating due to enlargement of the prostate gland

Stop use and ask a doctor if:
- Nervousness, dizziness, or sleeplessness occur
- Cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition
- New symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
Do not exceed recommended dosage.

Other information
Store at 15°-30°C (59°-86°F).

Capmist DM is a light green, oblong, capsule shaped, scored tablet, debossed with "CAP" and "DM" on one side and blank on the other.

Contains color additives including FD&C Yellow No. 5 (tartrazine).

Supplied in a light, light-resistant container with a child-resistant cap.

Questions? Comments?
Serious side effects may be reported to this number. Call 1 (814) 688-4022.

Manufactured:
Capital Pharma
Powell, OH 43065

Manufactured by:
Great Southern Laboratories
Houston, TX 77099

Rev. 02/12
dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride tablet

### Product Information

<table>
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<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
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<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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### Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td><strong>Dextromethorphan Hydrobromide</strong> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)</td>
<td>Dextromethorphan Hydrobromide</td>
<td>30 mg</td>
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<tr>
<td><strong>Guaifenesin</strong> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)</td>
<td>Guaifenesin</td>
<td>400 mg</td>
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<tr>
<td><strong>Pseudoephedrine Hydrochloride</strong> (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDBF)</td>
<td>Pseudoephedrine Hydrochloride</td>
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### Inactive Ingredients

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<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>Croscarmellose Sodium (UNII: M28OL1HH48)</td>
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<tr>
<td>Hypromelloses (UNII: 3NXW29V3WO)</td>
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<tr>
<td>Silicon Dioxide (UNII: ETJ7Z6XBU4)</td>
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<td>Cellulose, Microcrystalline (UNII: OP1R32D61U)</td>
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<td>Stearic Acid (UNII: 4ELV7Z65AP)</td>
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<td>Maltodextrin (UNII: 7CVR7L4A2D)</td>
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<td>Povidones (UNII: FZ989GH94E)</td>
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### Product Characteristics

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<tr>
<th>Color</th>
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<tr>
<td>Score</td>
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<tr>
<td>Shape</td>
<td>CAPSULE</td>
</tr>
<tr>
<td>Size</td>
<td>19mm</td>
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<tr>
<td>Flavour</td>
<td>Imprint Code</td>
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<tr>
<td>Imprint Code</td>
<td>CAP;DM</td>
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### Packaging

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<th>Package Description</th>
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<th>Marketing End Date</th>
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<tr>
<td>1</td>
<td>NDC:29978-606-90</td>
<td>90 in 1 BOTTLE</td>
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### Marketing Information

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<th>Application Number or Monograph Citation</th>
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<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>07/27/2011</td>
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**Labeler** - Capital Pharmaceutical (831545541)

**Registrant** - Pernix Manufacturing, LLC (078641814)
## Establishment

<table>
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<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<tr>
<td>Pernix Manufacturing, LLC dba Great Southern Laboratories</td>
<td></td>
<td>078641814</td>
<td>manufacture(29978-606)</td>
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Revised: 2/2013

Capital Pharmaceutical