

**MULTI-SYMPTOM MAPAP COLD FORMULA- acetaminophen,  
dextromethorphan hbr, phenylephrine hcl tablet, film coated  
Proficient Rx LP**

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**Major 44-470C-CMS**

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Nasal decongestant

***Uses***

- temporarily relieves these common cold/flu symptoms:
  - o minor aches and pains
  - o headache
  - o nasal congestion
  - o cough
  - o sore throat
  - o sinus congestion and pressure
- helps clear nasal passages
- promotes nasal and sinus drainage
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

## **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 using this product.

## **Ask a doctor before use if you have**

- liver disease
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

## **Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin.

## **When using this product**

**do not exceed recommended dosage.**

## **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

## **If pregnant or breast-feeding,**

ask a health professional before use.

## **Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## ***Directions***

- **do not take more than directed (see overdose warning)**
- adults and children 12 years and over:
  - o take 2 caplets every 4 hours
  - o swallow whole - do not crush, chew, or dissolve
  - o do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

### ***Other information***

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, croscarmellose sodium, crospovidone, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silica gel, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**(800) 616-2471**

### **Principal Display Panel**

**Major<sup>®</sup>**

NDC 63187-652-24

**MULTI-SYMPTOM**

**Mapap<sup>®</sup>**

**COLD FORMULA**

**CAPLETS**

**ASPIRIN FREE**

**ACETAMINOPHEN**

DEXTROMETHORPHAN HBr

PHENYLEPHRINE HCl

**DAYTIME • NON-DROWSY**

Pain Reliever / Fever Reducer

Cough Suppressant • Nasal Decongestant

For Relief of: Fever, Headache,  
Sore Throat, Nasal Congestion, Coughing

**24 CAPLETS** with Cool Blast Flavor

Compare to active ingredients in **TYLENOL<sup>®</sup> Cold Multi-Symptom Daytime\***

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Cold Multi-Symptom Daytime. 50844 REV0213D47008

Distributed by **MAJOR® PHARMACEUTICALS**  
 31778 Enterprise Drive  
 Livonia, MI 48150 USA M-17 Rev.02/13

Relabeled by **Proficient Rx LP**

Thousand Oaks, CA 91320

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**



Scan Here  NDC 63187-652-24 Relabeled By: Proficient Rx LP  
 Thousand Oaks, CA 91320

**Mapap Cold Formula**  
**#24 Tablets**

Each tablet contains: Acetaminophen 325mg Pain reliever / fever reducer; Dextromethorphan HBr 10mg Cough suppressant; Phenylephrine HCl 5mg Nasal decongestant

*White, oval shaped, unscored tablets with imprint code "44 470"*

Product ID: RM065224  
 Dist. By: Major Pharmaceuticals 17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 USA  
 Store at 25°C (77°F)

Keep medication out of the reach of children

Mapap Cold Formula #24 Tablets Lot #:00000 SN# MASTER Exp:00/00/00  
 NDC 63187-652-24

Mapap Cold Formula #24 Tablets Lot #:00000 SN# MASTER Exp:00/00/00  
 NDC 63187-652-24

Mapap Cold Formula #24 Tablets Lot #:00000 SN# MASTER Exp:00/00/00  
 NDC 63187-652-24

 GTIN: 00363187652241  
 SN# MASTER  
 Exp: 00/00/00  
 Lot #: 00000

**MULTI-SYMPATOM MAPAP COLD FORMULA**

acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, film coated

**Product Information**

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63187-652(NDC:0904-5786) |
| <b>Route of Administration</b> | ORAL           |                           |                              |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength             | Strength |
|--|-------------------------------|----------|
| <b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 325 mg   |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg    |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)      | PHENYLEPHRINE HYDROCHLORIDE   | 5 mg     |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                     |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                             |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                 |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)       |          |
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)            |          |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)               |          |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A) |          |
| <b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)   |          |
| <b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)            |          |

## Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | WHITE   | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL    | <b>Size</b>         | 17mm     |
| <b>Flavor</b>   | MENTHOL | <b>Imprint Code</b> | 44;470   |
| <b>Contains</b> |         |                     |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63187-652-24 | 2 in 1 CARTON   | 02/01/2016           |                    |
| 1 |                  | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 07/15/2005           |                    |

**Labeler** - Proficient Rx LP (079196022)

## Establishment

| Name             | Address | ID/FEI    | Business Operations |
|------------------|---------|-----------|---------------------|
| Proficient Rx LP |         | 079196022 | RELABEL(63187-652)  |