MUCUS RELIEF SINUS PRESSURE PAIN AND COUGH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated CHAIN DRUG MARKETING ASSOCIATION INC

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.

QCH-1199-2020-1207

Drug Facts

| Active ingredients (in each caplet) | Purpose |
|-------------------------------------|--------------------|
| Acetaminophen 325 mg | Pain reliever |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 200 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- temporarily relieves:
 - headache
 - nasal congestion
 - minor aches and pains
 - sinus congestion and pressure
 - cough
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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 taking this product.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product do not use more than directed

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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 right away (1-800-222-1222). 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)

- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

■ store between 20-25°C (68-77°F) in a dry place

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-587-20

QUALITY CHOICE®

†Compare to the Active Ingredients in MUCINEX® Fast-Max® Pressure, Pain & Cough

Maximum Strength

Mucus Relief Sinus Pressure, Pain & Cough

Pain Reliever, Cough Suppressant, Expectorant, Nasal Decongestant

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCl

Relieves Sinus Pressure & Congestion

Relieves Headache

Controls Cough

Thins & Loosens Mucus

Actual Size

20 CAPLETS

www.qualitychoice.com Questions: 800-935-2362 Distributed by C.D.M.A., Inc.®

Maximum Strength Per 4-Hour Dose

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

(1-800-222-1222). Ouick medical attention is critical for adults as well as for children even if y damage. In case of overdose, get medical help

1-800-222-1222).

do not notice any signs or symptor

contact a Poison Control Center right away

Directions a do not take more that

do not take more than 12 caplets in any

24-hour perrod

directed (see Overdose warning)

recommended dose (overdose) may cause liver

Overdose waming: Taking more than the

Keep out of reach of children.

professional before use.

TThis product is not manufactured or distributed by Rechill Benchiser, distributor of Mucinex® Sinus-Max® Pressure, Pain & Cough.

8

For Ages 12+

Mucus Relief Sinus Pressure, Pain & Cough

 persistent or chronic cough such as occurs with smoking, astima, drionic bronchilis, or emphysem **Drug Facts** (continued)

When using this product do not use more than directs ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days
■ fever gets worse or lasts more than 3 days
■ redness or savelling is present. nervousness, dizziness, or sleeplessness occu Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin Stop use and ask a doctor if Deutromethorphan HBr 10 mg... Cough suppressant

 nasal congestion
 minor aches and pains promotes nesal and/or sinus drainage helps toosen phlegm (mucus) and thin bronchial ■ cough sinus congestion and pressure JSes a temporarily relieves: Prenylephrine HCI 5 mg.

secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

iver waming: This product contains acetaminoph Warnings

These could be signs of a serious condition. If pregnant or breast-feeding, ask a health

cough comes back or occurs with rash or

headache that lasts

new symptoms occur

more than 12 caplets in 24 hours, which is the with other drugs containing acetaminophen
 3 or more alcoholic drinks daily while using Severe liver damage may occurif you take this product

fla skin reaction occurs, stop use and seek medic Allergy alert: Acetaminophen may cause severa skin reactions. Symptoms may include:

help right away

(prescription or norprescription). If you are not sure whether a drug contains acetaminophen, with any other drug containing acetaminophen ask a doctor or pharmacist.

adults and children 12 years of age and over take 2 caplets every 4 hours
 children under 12 years of age: do not use

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

store between 20-25°C (88-77°F) in a dry place
 retain outer package for complete product

Other information

lak a doctor before use if you have a diabetes or pharmacist before taking this product.

liver decase high blood pressure thyroid decase

For Ages 12+

matodentrin, microcrystalline cellulose, polyethyler

glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium diciode

cough that occurs with too much phiegm (muass)

touble uninating due to an enlarged prostate

crospovidone, FD&C red #40 aluminum lake, FD&C

diacide, com starch, croscamellose sodium,

jellow #6 aluminum lake, magnesium stearate



F1199020CH

Active ingredients (in each caplet) Purpose

Maximum Strength

Qualfenesin 200 mg.

Mucus Relief Sinus Pressure, Pain & Cough

Pain Reliever, Cough Suppressant, Expectorant, Nasal Decongestant

NDC 63868-587-20

*Compare to Active Ingredients in MUCINEX' Sinus-Max' Pressure, Pain & Cough

Maximum Strength

For Ages 12+ **Mucus Relief Sinus** Pressure, Pain & Cough

Pain Reliever, Cough Suppressant, Expectorant, Nasal Decongestant

Acetaminophen, Dextromethorphan HBr, Guaifenesin, Phenylephrine HCI

Relieves Sinus Pressure & Congestion Relieves Headache Controls Cough Thins & Loosens Mucus

Actual Size



20 CAPLETS

MUCUS RELIEF SINUS PRESSURE PAIN AND COUGH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-587 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration ORAL

| Active Ingredient/Active Moiety | | | |
|--|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN | 325 mg | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg | |

| Inactive Ingredients | | | |
|---|----------|--|--|
| Ingredient Name | Strength | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48) | | | |
| CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561) | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | | | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | |
| TALC (UNII: 7SEV7J4R1U) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |

| Product Characteristics | | | | |
|-------------------------|------|--------------|----------|--|
| Color | red | Score | no score | |
| Shape | OVAL | Size | 19mm | |
| Flavor | | Imprint Code | AAA;1165 | |
| Contains | | | | |

| Packaging | | | |
|------------|---------------------|-----------------|---------------|
| # Hom Codo | Packago Docerintian | Marketing Start | Marketing End |

| # | item Code | Раскаде резсприон | Date | Date |
|---|----------------------|---|------------|------|
| 1 | NDC:63868- 587-20 | 2 in 1 CARTON | 12/01/2020 | |
| 1 | | 10 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 final | part341 | 12/01/2020 | |
| | | | |

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 12/2022 CHAIN DRUG MARKETING ASSOCIATION INC