

MAXIMUM STRENGTH MAX COLD AND SINUS- acetaminophen, guaifenesin, phenylephrine hcl liquid
AptaPharma Inc.

Maximum strength Max Cold & Sinus

Drug Facts

Active ingredients
(in each 20 mL)

Acetaminophen 650 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purpose

Acetaminophen Pain reliever/Fever reducer

Guaifenesin Expectorant

Phenylephrine HCl Nasal decongestant

Uses

temporarily relieves these common **cold and flu symptoms**:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- sore throat
- headache
- fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Liver warning

This product contains acetaminophen.

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

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.

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 taking this product.
- for children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or 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 use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. 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. In case of overdose, get medical help or contact a Poison Control Center right away.

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as recommended (see Overdose warning)
- use dosage cup
- mL =milliliter

- do not take more than 6 doses in any 24-hour period

| Age | Dose |
|--------------------------------------|---------------------|
| Adults & children 12 years and older | 20 mL every 4 hours |
| Children under 12 years of age | Do not use |

Other information

- each 20 mL contains: sodium 10 mg
- dosage cup provided
- store between 15-30°C (59-86°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, Xanthan gum

Questions? Call weekdays from 9:30AM to 4:30 PM EST **1-877-798-5944**

Maximum Strength MAX COLD & SINUS

AP SAFE NDC 76281-515-25

Compare to Mucinex® FAST-MAX™ Cold & Sinus
Active ingredients*

**Maximum Strength
MAX COLD & SINUS**

**Acetaminophen /
Pain reliever/Fever Reducer
Guaifenesin /Expectorant
Phenylephrine HCl / Nasal decongestant
Cold & Sinus**

Relief of:

- **Fever & Bodyaches**
- **Thins & Loosens Mucus**
- **Nasal & Chest Congestion**

**Adults- For Ages 12 and over
6 FL OZ (177 mL)**

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Failure to follow these warnings could result in serious consequences.

Manufactured by:
AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110

* This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Mucinex® FAST-MAX™ Cold & Sinus.



Drug Facts (continued)

- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or 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 use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleepiness occur
- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage.

Peel Corner to Read Complete Drug Facts and Information



DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Failure to follow these warnings could result in serious consequences

Manufactured by:
AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110



3 76281 51525 1

AP-LB-001

Lot: Exp:

Drug Facts

Active Purpose Ingredients (in each 20 mL)

Acetaminophen 650 mg
Pain reliever/Fever reducer

Guaifenesin 400 mg Expectorant

Phenylephrine HCl 10 mg Nasal decongestant

Uses

temporarily relieves these common cold and flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- sore throat ■ headache ■ fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Liver warning: This product contains acetaminophen. 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

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

Drug Facts (continued)

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

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 taking this product.

- for children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- high blood pressure
- diabetes

res

MAXIMUM STRENGTH MAX COLD AND SINUS

acetaminophen, guaifenesin, phenylephrine hcl liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76281-515 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|----------------------------------------------------------------------------------|------------------------------------------|-------------------------------------------------------|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 650 mg in 20 mL | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | | GUAIFENESIN | 400 mg in 20 mL | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 20 mL | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | | | | |
| WATER (UNII: 059QF0KOOR) | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | | |
| Product Characteristics | | | | |
| Color | blue | Score | | |
| Shape | | Size | | |
| Flavor | | Imprint Code | | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:76281-515-25 | 177 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/30/2024 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M012 | 01/30/2024 | | |

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|------------------------|
| AptaPharma Inc. | | 790523323 | manufacture(76281-515) |

Revised: 1/2024

AptaPharma Inc.