TYLENOL COLD PLUS FLU SEVERE- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated Morning Star OTC

TYLENOL [®] Cold + Flu Severe

Drug Facts

| Active ingredients (in each caplet) | Purpose |
|-------------------------------------|---------------------|
| Acetaminophen 325 mg | Pain reliever/fever |
| Acelaninophen 323 mg | reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Guaifenesin 200 mg | Expectorant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- for the temporary relief of the following cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- 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

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.

• if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

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

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

When using this product do not exceed recommended dose

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

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)

| adults and children 12 years and over | take 2 caplets every 4 hours swallow whole; do not crush, chew or dissolve do not take more than 10 caplets in 24 hours |
|--|---|
|--|---|

children under 12 years ask a doctor

Other information

- each caplet contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if blister unit is torn or broken

Inactive ingredients

carnauba wax, croscarmellose sodium, D&C yellow no. 10 aluminum lake, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sucralose, titanium dioxide

Questions or comments?

call 1-877-895-3665(toll-free) or 215-273-8755(collect)

Repackaged by:

Morning Star OTC

145 S. Anderson St, Los Angeles,

CA 90033

PRINCIPAL DISPLAY PANEL-2 Tablets



PRINCIPAL DISPLAY PANEL-2 Tablets x 25 Pouches



TYLENOL COLD PLUS FLU SEVERE

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

| Product Information | | | | | | | |
|-------------------------|----------------|--------------------|-------------------------------|--|--|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53209-1003(NDC:50580-402) | | | | |
| 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) | GUAIFENES IN | 200 mg | | | | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - | PHENYLEPHRINE | E man | | | | |

| Ingredient Name | | | | | | | | Strength | |
|---|-----------------------|---------|--|-----------|----------------------------|------------|-----------------------|-----------------------|--|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | | | | | | |
| CF | ROSCARMELLOS | SE SOD | DIUM (UNII: | M28OL1H | IH48) | | | | |
| D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6) | | | | | | | | | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | | | | | | | | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | | | | | | | |
| M | AGNESIUM STE | ARATE | (UNII: 7009 | 7M6I30) | | | | | |
| M | CROCRYSTALLI | NE CE | LLULOSE(| UNII: OP1 | .R32D61U) | | | | |
| PC | DLYETHYLENE G | SLYCO | L, UNSPEC | IFIED (UI | NII: 3WJQ0SDW1A) | | | | |
| 5ι | JCRALOSE (UNII: | 96K6U | IQ3ZD4) | | | | | | |
| Гľ | TANIUM DIOXID | E (UNII | : 15FIX9V2J | P) | | | | | |
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| P | roduct Char | acter | ristics | | | | | | |
| Co | olor | | yellow | Sco | ore | no score | | | |
| Sł | nape | | OVAL | Siz | е | | 19mm | | |
| FI | avor | | | Imp | Imprint Code TYLENOL;SEVER | | E | | |
| Co | ontains | | | | | | | | |
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| Pa | ackaging | | | | | | | | |
| # | Item Code | | Package Description | | Marketing Start Date | | Marketing End Date | | |
| 1 | NDC:53209- 1003-2 | 25 in | 25 in 1 POUCH | | | 06/19/2025 | | | |
| 1 | NDC:53209- 1003-1 | | 2 in 1 BLISTER PACK; Type 0: Not a Combination Product | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Ν | larketing | Info | ormatio | on | | | | | |
| | Marketing Category | | | on Numl | ber or Monograph ation | Mar | keting Start Date | Marketing End Date | |
| | | | | 0.10 | | | 2440 | 2400 | |

Labeler - Morning Star OTC (078589357)

Registrant - Morning Star OTC (078589357)

| Establishment | | | | | | | |
|------------------|---------|-----------|----------------------------|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | |
| Morning Star OTC | | 078589357 | repack(53209-1003) | | | | |