

TYLENOL COLD MAX DAY- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride tablet, film coated
Johnson & Johnson Consumer Inc.

TYLENOL Cold Max

Day

Drug Facts

| <i>Active ingredients (in each caplet)</i> | <i>Purpose</i> |
|---|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

- temporarily relieves these common cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - 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

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 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 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 | <ul style="list-style-type: none">▪ 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

- store between 20-25°C (68-77°F)
- **do not use if blister unit is torn or broken**

Inactive ingredients

anhydrous citric acid, carnauba wax, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, modified starch, potassium sorbate, powdered cellulose, pregelatinized starch, sodium benzoate, sodium citrate, sodium starch glycolate, sucralose

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 50580-515-02

TYLENOL[®]
FOR ADULTS
COLD MAX

Acetaminophen,
Dextromethorphan HBr, Phenylephrine HCl
Pain Reliever-Fever Reducer, Cough Suppressant,
Nasal Decongestant

DAY NON-DROWSY

- HEAD + BODY ACHES
- FEVER + SORE THROAT
- COUGH
- NASAL CONGESTION

Actual Size

24 CAPLETS

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PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

How can we help?
1-877-895-3665





NDC 50580-515-02

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Important: Read all product information before using. Keep this box for important information.

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

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TYLENOL COLD MAX DAY

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

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50580-515 |
| Route of Administration | ORAL | | |

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

| Inactive Ingredients | | |
|---|--|----------|
| Ingredient Name | | Strength |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | | |
| POWDERED CELLULOSE (UNII: SMD1X3XO9M) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | | |
| SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D) | | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--------------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 18mm |
| Flavor | MINT | Imprint Code | TYLENOL;1078 |
| Contains | | | |

| Packaging | | | |
|-----------|--|-----------------|---------------|
| | | Marketing Start | Marketing End |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|-----------------------|------------------|---|----------------------|--------------------|
| 1 | NDC:50580-515-01 | 2 in 1 CARTON | 07/15/2015 | 08/31/2021 |
| 1 | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:50580-515-02 | 2 in 1 CARTON | 12/21/2018 | 01/31/2025 |
| 2 | | 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 | 07/15/2015 | 01/31/2025 |

Labeler - Johnson & Johnson Consumer Inc. (878046358)