

**MAXIMUM STRENGTH DAY COLD AND FLU AND NIGHT SEVERE COLD AND FLU-
acetaminophe, dextromethorphan hbr, guaifenesin, phenylephrine hcl,
triprolidine hcl tablets
TIME CAP LABORATORIES,INC**

**49483-726_Timely_Maximum strength Day cold & flu and Night severe cold &
flu Tablets**

Drug Facts

Active ingredients (in each caplet)

Day Cold & Flu

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Active ingredients (in each caplet)

Night Severe Cold & Flu

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg
Triprolidine HCl 1.25 mg

Purposes

Day Cold & Flu

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Purposes

Night Severe Cold & Flu

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant
Antihistamine

Uses

Day Cold & Flu

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

- o sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Night Severe Cold & Flu

- temporarily relieves these common cold and flu symptoms:
 - o cough
 - o nasal congestion
 - o minor aches and pains
 - o sore throat
 - o headache
 - o sneezing
 - o sinus congestion and pressure
 - o runny nose
 - o itching of the nose or throat
 - o itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 4,000 mg 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.

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.

Ask a doctor before use if you have

- liver disease
- heart disease

- diabetes
- high blood pressure
- thyroid disease
- glaucoma (**Night Severe Cold & Flu only**)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (**Night Severe Cold & Flu only**)
- 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 are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (**Night Severe Cold & Flu only**)

When using this product

- **do not use more than directed**
- excitability may occur, especially in children (**Night Severe Cold & Flu only**)
- marked drowsiness may occur (**Night Severe Cold & Flu only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**Night Severe Cold & Flu only**)
- avoid alcoholic drinks (**Night Severe Cold & Flu only**)
- use caution when driving a motor vehicle or operating machinery (**Night Severe Cold & Flu only**)

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 fever, 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

Day Cold & Flu

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49483-726-64 | 4 in 1 CARTON | 09/21/2023 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 4 BLISTER PACK | 24 in 4 |
| Part 2 | 4 BLISTER PACK | 16 in 4 |

Part 1 of 2

MAXIMUM STRENGTH DAY COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablets tablet

Product Information

| | |
|-------------------------|---------------|
| Item Code (Source) | NDC:49483-733 |
| Route of Administration | ORAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------|
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POVIDONE (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TALC (UNII: 7SEV7J4R1U) | |

| | |
|--|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |

Product Characteristics

| | | | |
|-----------------|---------------------------------|---------------------|----------|
| Color | red (Light red to red) | Score | no score |
| Shape | CAPSULE (Capsule shaped tablet) | Size | 19mm |
| Flavor | | Imprint Code | D1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 6 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 | 09/21/2023 | |

Part 2 of 2

MAXIMUM STRENGTH NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl tablets tablet

Product Information

| | |
|--------------------------------|---------------|
| Item Code (Source) | NDC:49483-734 |
| Route of Administration | ORAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|----------|
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM) | TRIPROLIDINE HYDROCHLORIDE | 1.25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| MICA (UNII: V8A1AW0880) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| POVIDONE (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|---|---------------------|----------|
| Color | yellow (Light golden yellow to Golden yellow) | Score | no score |
| Shape | CAPSULE (Capsule shaped tablet) | Size | 19mm |
| Flavor | | Imprint Code | N1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 4 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 | 09/21/2023 | |

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| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 09/21/2023 | |

Labeler - TIME CAP LABORATORIES,INC (037052099)

Registrant - TIME CAP LABORATORIES,INC (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| MARKSANS PHARMA LIMITED | | 925822975 | manufacture(49483-726) |

