

**COLD AND FLU NIGHTTIME SEVERE- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled
TARGET CORP**

11673-983 TARGET COLD AND FLU NIGHTTIME SEVERE

Drug Facts

Active ingredients(in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

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

- more than 8 softgels in 24 hours, which is the maximum daily amount for this product
- 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.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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.

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

- take only as directed
do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over: 2 softgels with water every 4 hrs

children 4 to under 12 yrs: ask a doctor

children under 4 yrs: do not use

Other information

- do not exceed 25°C

FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?

Call 1-800-910-6874

Product packaging for Severe Nighttime Cold & Flu. Includes Drug Facts, Warnings, Directions, and Active Ingredients sections. Features a yellow arrow logo and 'up&up' branding.

COLD AND FLU NIGHTTIME SEVERE

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11673-983 |
| 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 |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POVIDONE (UNII: FZ989GH94E) | |
| SHELLAC (UNII: 46N107B71O) | |
| SORBITOL (UNII: 506T60A25R) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| GELATIN (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | green | Score | no score |
| Shape | BULLET | Size | 16mm |
| Flavor | | Imprint Code | 72 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:11673-983-08 | 1 in 1 CARTON | 06/01/2020 | |
| 1 | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

| 2 | NDC:11673-983-24 | 2 in 1 CARTON | 06/01/2020 | |
|------------------------------|--|---|----------------------|--------------------|
| 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 | | 06/01/2020 | |

Labeler - TARGET CORP (006961700)

Registrant - TIME CAP LABS INC (037052099)

| Establishment | | | |
|----------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| MARKSANS PHARMA LTD | | 925822975 | manufacture(11673-983) |

Revised: 9/2024

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