

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

KROGER 626T NIGHTTIME SEVERE COLD AND FLU

- Acetaminophen
- PhenylephrineHCl,
- Doxylamine Succinate
- Dextromethorphan HBr

FD&C BLUE #1, GELATIN, GLYCERIN, POLYETHYLENE GLYCOL, POVIDONE, PROPYLENE GLYCOL, PURIFIED WATER, SHELLAC, SORBITOL SORBITAN SOLUTION, TITANIUM DIOXIDE

- 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

take only as directed

do not exceed 8 Softgels per 24 hours

- adults & children 12 yrs & over 2 Softgels with water every 6 hrs
- children 4 to under 12 yrs ask a doctor
- children under 4 yrs do not 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.

Liver warning

This product contains acetaminophen.

Severe liver damage may occur if you take

more than 8 Softgels in 24 hrs, 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.



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Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41226-626 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--|--|----------------------|--------------------|
| Ingredient Name | | Basis of Strength | Strength | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg | |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 325 mg | |
| DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | | DOXYLAMINE SUCCINATE | 6.25 mg | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | | PHENYLEPHRINE HYDROCHLORIDE | 5 mg | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| SHELLAC (UNII: 46N107B71O) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | | | | |
| GELATIN (UNII: 2G86QN327L) | | | | |
| WATER (UNII: 059QF0K00R) | | | | |
| SORBITOL (UNII: 506T60A25R) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| 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:41226-626-08 | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | 11/16/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part341 | 05/29/2020 | | |

Labeler - KROGER(006999528)

Registrant - TIME CAP LABS INC (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| MARKSANS PHARMA LTD | | 925822975 | manufacture(41226-626) |

