

**DAYTIME-NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
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 627T DAY-NIGHT SEVERE COLD AND FLU

**COLD AND FLU DAYTIME SEVERE SOFTGELS (625T)
DRUG FACTS**

Active ingredients (in each softgel)
ACETAMINOPHEN 325MG
D0EXTROMETHORHAN HBR10 MG,
GUAIFENESIN 200 MG
, PHENYLEPHRINE HCL 5 MG

- temporarily relieves common cold/flu symptoms:
 - nasal congestion
 - sinus congestion & pressure
 - cough due to minor throat & bronchial irritation
 - minor aches & pains
 - headache
 - fever
 - sore throat
 - reduces swelling of nasal passages
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.
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Warnings

Liver warning - This product contains acetaminophen. Severe liver damage may occur if you take - more than 8 softgels

This product contains acetaminophen.

Severe liver damage may occur if you take more than 8 LiquiCaps 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.

FD&C Blue No.1,FD&C Red No. 40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac,sorbitol sorbitan solution, titanium dioxide

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
-

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. (1800-222-1222)

Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

PAIN RELIEVER-FEVER REDUCER

COUGH SUPPRESSANT

MINOR ACHES AND PAINS

CHEST CONGESTION

COLD AND FLU NIGHTTIME SEVERE SOFTGELS (626T)

DRUG FACTS

3 (in each softgel)

Acetaminophen 325mg

Dextromethorphan HBR 10 mg

Doxylamine Succinate 6.25 mg

PhenylephrineHCl,

Purpose

- Pain reliever/Fever reducer
 - Cough suppressant
 - Antihistamine
 - Nasal decongestant
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MINOR ACHES AND PAINS, FEVER

NASAL CONGESTION AND SINUS PRESSURE

SNEEZING, RUNNY NOSE

COUGH

Minor Aches & Pains

Nasal/Sinus Congestion

& Sinus Pressure

Sneezing, Runny Nose

Cough

Warnings

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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:

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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.

Directions

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

FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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



DAYTIME-NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-627
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:41226-627-24	24 in 1 CARTON	06/03/2020
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	8
Part 2	1 BLISTER PACK	16

Part 1 of 2

NIGHTTIME SEVERE COLD AND FLU

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

Product Information

Item Code (Source)	NDC:41226-626
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

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

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		2 in 1 CARTON		
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 final	part341	05/29/2020	

Part 2 of 2

DAYTIME SEVERE COLD AND FLU

acetaminophen, phenylephrine hcl, dextromethorphan hbr, guaifenesin capsule, liquid filled

Product Information

Item Code (Source)	NDC:41226-625
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

POVIDONE (UNII: FZ989GH94E)

Product Characteristics

Color	orange	Score	no score
Shape	BULLET	Size	16mm
Flavor		Imprint Code	73
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 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 final	part341	05/29/2020	

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(41226-627)

Revised: 5/2020

KROGER