

ACETAMINOPHEN, DEXTROMETHORPHAN HBR, GUAIFENESIN, PHENYLEPHRINE HCL- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Kroger Company

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.

628TKROGER 41226-628

Active ingredients (in each softgel)

acetaminophen 325 mg - Dextromethorphan HBr 10mg - Guaifenesin 200 mg - Phenylephrine HCl 5 mg

INACTIVE INGREDIENTS

Inactive ingredients: FD&C yellow#6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

PURPOSE

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

INDICATIONS & USAGE

temporarily relieves these common cold and flu symptoms: nasal congestion - headache - cough - minor aches and pains - sore throat - temporarily reduces fever - promotes nasal and/or sinus drainage - helps

...

temporarily relieves these common cold and flu symptoms:

nasal congestion
headache
cough
minor aches and pains
sore throat

temporarily reduces fever
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

DOSAGE & ADMINISTRATION

Directions

Do not take more than directed (see Overdose warning) do not take more than 12 SOFTGELS in any 24-hour period \

adults and children 12 years of age and over: take 2 SOFTGELS every 4 hours

children under 12 years of age: do not use

KEEP OUT OF REACH OF CHILDREN

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 ...

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.

Warnings

Liver warning - This product contains acetaminophen. Severe liver damage may occur if you take: more than 12 softgels in 24 hours, which is the maximum daily amount - with other drugs ...

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

more than 12 softgels 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.



ACETAMINOPHEN, DEXTROMETHORPHAN HBR,

GUAILFENESIN,PHENLYEPHRINE HCL

acetaminophen, dextromethorphan hbr, guailfenesin,phenlyeprine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-628
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
WATER (UNII: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	78
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-628-16	16 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/21/2020	

Labeler - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
marksans pharma ltd		925822975	manufacture(41226-628)

Revised: 12/2020

Kroger Company