#### NON DROWSY DAYTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride 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.

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#### Non Drowsy Daytime Cold and Flu Softgel - 48ct

#### **Drug Facts**

Active ingredients (in each Softgel)	Purposes
Acetaminophen 325 mg	Pain reliever / Fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever

#### Warnings

#### Liver warning

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- 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, lasts 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
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

# Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

#### When using this product, do not use more than directed.

#### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough get worse or last 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.

#### **Overdose warning**

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

#### Directions

take only as directed - see Overdose warning

• do not exceed 4 doses per 24 hrs

adults & children 12 yrs &	2 softgels with water
over	every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### **Other information**

store at room temperature between 20-25 °C (68-77 °F)

#### Inactive ingredients

FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

#### **Questions or comments**

1-800-632-6900

#### **PRINCIPAL DISPLAY PANEL - 48 Softgel Blister Pack Carton**

COMPARE TO the active ingredients of VICKS<sup>®</sup> DAYQUIL<sup>™</sup> COLD & FLU RELIEF LIQUICAPS<sup>™</sup> \*See bottom panel

NDC 30142-768-48

POWERFUL NON-DROWSY RELIEF

Kroger<sub>®</sub>

OUR PHARMACIST RECOMMENDED

Cold & Flu DayTime Multi-Symptom Relief

Acetaminophen Dextromethorphan HBr Phenylephrine HCl

actual size

Pain Reliever Fever Reducer Cough Suppressant Nasal Decongestant

48 SOFTGELS



Love It or Your Money Back.

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#### UII CIII σ STNJGAG TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN Drug Facts Active ingredients (in each Softgel) Purposes See a ain reliever / Fever reducer ophen 325 OHO Dextromethorphan HBr 10 mg. Cough suppressant Phenylephrine HCl 5 mg. Nasal decongestant More Prod ROGER INNATI, nformation. Uses: J temporarily relieves common cold/flu symptoms: z cough due to minor throat & bronchial irritation sore throat nasa concestion MADE C NC minor aches & pains headache fever P Ca 2 Warnings: Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 doses in 24 hrs, which is the maximum daily amount for this product with other drugs containing acetaminophen FD&C red #40, FD&C vellow #6, geltatin, glycerin, polyethylene glycol, povidone, propylene glycol purified water, sorbitol sorbitan solution, titanium dioxide 3 or more alcoholic drinks daily while using this product Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: 2 softgels with water every 4 hrs ask a doctor skin reddening blisters rash If a skin reaction occurs, stop use and seek medical help right away. exceed 4 doses per 24 hrs Sore throat warning: If sore throat is severe, lasts 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 do not use 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. not store at room temperature between 20-25 °C (68-77 °F) Ask a doctor before use if you have ver disease heart disease thyroid disease diabetes 9 high blood pressure trouble urinating due to enlarged prostate gland cough that occurs with too Questions or comments: 1-800-632-6900 much phlegm (mucus) persistent or chronic cough as occurs with smoking, asthma, or emphysema varning Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin. When using this product, do not use more than directed, take only as directed - see Overdose Stop use and ask a doctor if you get nervous, dizzy or sleepless pain, nasal congestion or cough get Drug Facts (continued) adults & children 12 yrs & over children 4 to under 12 yrs children under 4 yrs worse or last 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 Inactive ingredients: could be signs of a serious condition. Other information. If pregnant or breast-feeding, ask a health professional before use, Keep out of reach of children, Directions: Overdose warning: Taking more than directed can cause serious health problems. 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 & for children even if you do not notice any signs or symptoms. ► PLEASE RECYCLE CT3014276848 REV.00-012021 1260 01255 0 6 LOT: EXP:

COMPLETE WARNINGS AND PRODUCT INFORMATION

KEEP OUTER CARTON FOR

AND

READ

#### NON DROWSY DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:3014	2-768	
Route of Administration	ORAL					
Active Ingredient/Active	Molety					
Ingredient Name Basis of Streng					Strength	
Acetaminophen (UNII: 36209ITL9I	D) (Acetaminophen - UNII:30	6209ITL9D)	Acetaminophen		325 mg	
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - Dextromethorphan Hydrobromide UNII:7355X3ROTS)			in	10 mg		
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)Phenylephrine Hydrochloride			5 mg			
Inactive Ingredients						
Ingredient Name				St	Strength	
FD&C RED NO. 40 (UNII: WZ B912	7XOA)					
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)						
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)						
Glycerin (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL, UNSPE	CIFIED (UNII: 3WJQ0SDW1)	۹)				
POVIDONE, UNSPECIFIED (UNII: F	Z989GH94E)					
Propylene Glycol (UNII: 6DC9Q16	7V3)					

WATER (UNII: 059QF0K00R)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

#### **Product Characteristics**

Color	ORANGE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	786
Contains			

### Packaging

-	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:30142- 768-48	4 in 1 CARTON	05/01/2021	
	L	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC MONOGRAPH	part341	05/01/2021	

Revised: 1/2022

**KROGER COMPANY**