

KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate

The 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.

Kroger Daytime and Nighttime Cold and Flu Softgel

DayTime Cold & Flu

Drug Facts

Active ingredients (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever / Fever reducer

Cough suppressant

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, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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 • 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 (1-800-222-1222). 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 & 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:

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

Inactive ingredients:

Edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments:

1-800-632-6900

NightTime Cold & Flu

Drug Facts

Active ingredients (in each Softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purposes

Pain reliever / Fever reducer

Cough suppressant

Antihistamine

Uses:

temporarily relieves common cold/flu symptoms:

• cough due to minor throat & bronchial irritation • sore throat • headache • minor aches & pains • fever • runny nose & sneezing

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your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. • to make a child sleep

Ask a doctor before use if you have • liver disease • 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, & tranquilizers may increase drowsiness

Stop use and ask a doctor if • pain 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.

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Questions or comments:

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COMPARE TO the active ingredients of VICKS® DAYQUIL®/NYQUIL® COLD & FLU RELIEF LIQUICAPS® *See side panel

POWERFUL RELIEF

DAYTIME OR NIGHT TIME

OUR PHARMACIST RECOMMENDED

Multi-Symptom Relief

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DO NOT USE IF THE BLISTER IS TORN OR BROKEN OR SHOW ANY SIGNS OF TAMPERING

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

MADE IN UAE

For **More Product Information, Scan UPC**

Using Your **Kroger App** or Call 800-632-6900

Our Brands, Our Gurantee.

Love It or Your Money Back.

www.kroger.com

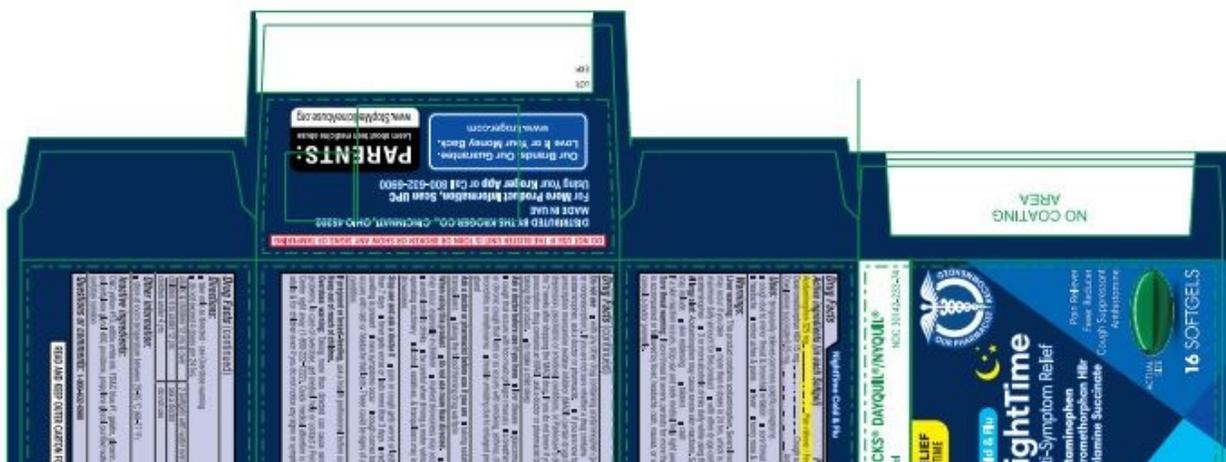
PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

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Packaging





FRONT PANEL



DRUG FACTS PANEL

Drug Facts	NightTime Cold & Flu	Drug Facts	DayTime Cold & Flu
Active ingredients (in each Softgel)	Purposes	Active ingredients (in each Softgel)	Purposes
Acetaminophen 325 mg.....	Pain reliever / Fever reducer	Acetaminophen 325 mg.....	Pain reliever / Fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant	Dextromethorphan HBr 10 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine	Phenylephrine HCl 5 mg.....	Nasal decongestant
Uses: temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose & sneezing 		Uses: temporarily relieves common cold/flu symptoms: <ul style="list-style-type: none"> ■ 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.		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.	
Drug Facts (continued)		Drug Facts (continued)	

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. ■ to make a child sleep

Ask a doctor before use if you have ■ liver disease ■ 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

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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, & tranquilizers may increase drowsiness

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Drug Facts (continued)

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Questions or comments: 1-800-632-6900

Drug Facts (continued)

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Edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol 400, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments: 1-800-632-6900

KROGER DAYTIME AND NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-233
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-233-74	1 in 1 KIT; Type 0: Not a Combination Product	08/31/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	4 BLISTER PACK	16

Part 1 of 2

KROGER DAYTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Item Code (Source)	NDC:30142-087
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

SORBITAN (UNII: 6O92ICV9RU)

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	807
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	08/31/2022	

Part 2 of 2

KROGER NIGHTTIME COLD AND FLU SOFTGEL

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:30142-086
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: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C00X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	808
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	08/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/31/2022	

Labeler - The Kroger Company (006999528)