

SHOPRITE NI CALM- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated

Wakefern Food Corporation

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.

ShopRite Ni-Calm Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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, 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an 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

- 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, and 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.

If pregnant or breast-feeding,

ask a health professional before use.

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.

Directions

- take only as directed – see overdose warning
- do not exceed 4 doses 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

Inactive Ingredients

D&C yellow no. 10, edible ink*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-800-SHOPRITE

Package/Label Principal Display Panel

Compare to: Active Ingredients in Vicks® NyQuil®

SEE NEW WARNINGS

NI-CALM

PAIN RELIEVER / FEVER REDUCER

Acetaminophen – Aches / Fever

COUGH SUPPRESSANT

Dextromethorphan HBr – Cough

ANTIHISTAMINE

Doxylamine Succinate – Sneezing / Runny Nose

Relieves major flu symptoms so you can rest

Multi-symptom – ALCOHOL FREE

actual size

16 softgels



Made in Canada

Distributed By: Wakefern Food Corp.
5000 Riverside Drive
Keasbey, NJ 08832 ©2015

**This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil®.



Your complete satisfaction
or your money back.
We welcome your questions
and comments.
Call: 1-800-ShopRite
or contact us:
www.shoprite.com

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Compare to: Active Ingredients in Vicks® NyQuil®**

SEE NEW WARNINGS



NI-CALM

PAIN RELIEVER/FEVER REDUCER

Acetaminophen....Aches/Fever

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Doxylamine Succinate....Sneezing/Runny Nose

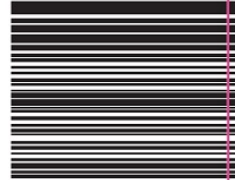
Relieves major flu symptoms so you can rest

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16 softgels



CONVENIENT RECLOSEING TAB



Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active ingredients (in each softgel)

Purpose

Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine

Uses temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- runny nose and sneezing
- sore throat
- headache
- fever

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

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Drug Facts (continued)

Questions or comments? 1-800-SHOPRITE

Store at 20-25°C (68-77°F).



Drug Facts (continued)

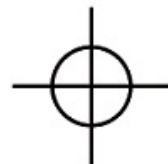
Directions ■ take only as directed – see overdose warning

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adults & children 12 yrs & over	2 softgels with water every 6 hrs
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Inactive ingredients D&C yellow no. 10, edible ink*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient ▶

OPEN OTHER END



: 05673 8B C2

SHOPRITE NI CALM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-056
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	GREEN (clear)	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	056
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-056-73	8 in 1 CARTON	05/12/2014	
1		2 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
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OTC monograph final

part341

05/12/2014

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2018

Wakefern Food Corporation