

SHOPRITE NI CALM COUGH- dextromethorphan hbr, doxylamine succinate solution
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 Cough Drug Facts

Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Cough suppressant

Antihistamine

Uses

temporarily relieves cold symptoms:

- cough due to minor throat and bronchial irritation
- runny nose and sneezing

Warnings

Do not use

- 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

- 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

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness

- 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

cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 32 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-SHOPRITE

Principal Display Panel

Compare to: Active Ingredients in Vicks® NyQuil® Cough

NI-CALM COUGH

COUGH SUPPRESSANT

Dextromethorphan HBr – Cough

ANTIHISTAMINE

Doxylamine Succinate – Sneezing/Runny Nose

All Night Cough Relief

Multi-symptom – 10% ALCOHOL

Cherry Flavor

12 FL OZ (355 mL)

Drug Facts (continued)

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Questions or comments? 1-800-SHOPRITE

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

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 Keasbey, NJ 08832
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 We welcome your questions and comments.
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PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org



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



NI-CALM

COUGH

COUGH SUPPRESSANT

Dextromethorphan HBr...Cough

ANTIHISTAMINE

Doxylamine Succinate...Sneezing/Runny Nose

All Night Cough Relief
Multi-symptom • 10% ALCOHOL



Cherry Flavor

12 FL OZ (355 mL)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each 30 mL)	Purpose
Dextromethorphan HBr 30 mg.....	Cough suppressant
Doxylamine succinate 12.5 mg.....	Antihistamine

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SHOPRITE NI CALM COUGH

dextromethorphan hbr, doxylamine succinate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-668
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	RED (Dark Red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-668-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/27/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/27/2013	

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2018

Wakefern Food Corporation