# GOOD SENSE NIGHT TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled L. Perrigo 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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#### **Perrigo Night Time 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?

1-800-719-9260

#### Package/Label Principal Display Panel

Multi-Symptom Relief

GREAT SIZE FOR TRAVEL

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Night Time

Cold & Flu

Actual Size

Headache, Fever, Sore Throat, Minor Aches & Pains

Sneezing, Runny Nose

Cough

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

Compare to active ingredients of Vicks® NyQuil® Cold & Flu

100% SATISFACTION GUARANTEED

8 Softgels

Powerful Nighttime Relief





## GOODSENSE.

Multi-Symptom Relief

NDC 0113-0056-51

#### GREAT SIZE FOR TRAVEL

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

# NightTime Cold & Flu

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

8 Softgels

### Acetaminophen,

Dextromethorphan HBr, Doxylamine Succinate

Compare to active ingredients of Vicks<sup>®</sup> NyQuil<sup>®</sup>Cold & Flu

Powerful Nighttime Relief





Allegan, MI 49010

®ogirri99

Na beaudinaid Made in Canada

#### DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN Drug Facts

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Acetaminophen 325 mg.

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■ a breathing problem such as emphysema or chronic bronchitis
■ liver disease

persistent or chronic cough as occurs with smoking, asthma, or emphysema.

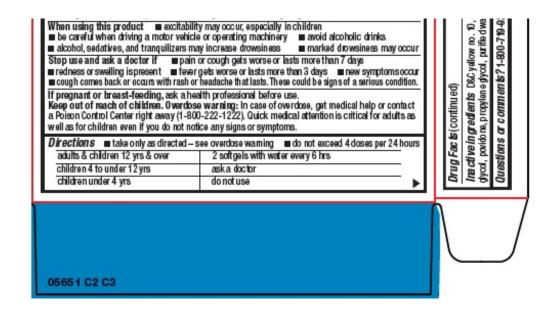
■ trouble urinating due to an enlarged prostate gland

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■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

Storeat20-29C (68-77P).

blein K\*,FD&Cblue no.1,gelafin, glycerin, polyet hylens , sorbibl sorbitan solu 1bon. \* may contain this hygedient



#### **GOOD SENSE NIGHT TIME**

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0056
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - 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: PDC6 A3C0 O X)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				

Product Characteristics				
Color	GREEN (clear)	Score	no score	

Shape	OVAL	Size	20 mm
Flavor		Imprint Code	056
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0113-0056-73	8 in 1 CARTON	05/30/2014	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0113-0056-62	12 in 1 CARTON	08/25/2014	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0113-0056-51	4 in 1 CARTON	08/10/2016	
3		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
OTC monograph final	part341	05/30/2014	

## Labeler - L. Perrigo Company (006013346)

Revised: 9/2020 L. Perrigo Company