

## **NIGHT TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate solution**

**H E B**

*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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### **HEB Night Time Drug Facts**

#### **Active ingredients (in each 30 mL)**

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 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, persists 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
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

### **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
- 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 39 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?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

Compare to Vicks® NyQuil® Cold & Flu active ingredients

H-E-B®

Nighttime

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistamine

Cold & Flu

Cherry Flavor

ALCOHOL 10%

Relief of:

- Pain
- Fever
- Cough
- Sneezing
- Runny Nose

12 FL OZ (355 mL)

Compare to  
Vicks® NyQuil®  
Cold & Flu  
active Ingredients\*

NDC 37808-459-40



# Nighttime

**Acetaminophen**  
Pain Reliever/Fever Reducer  
Dextromethorphan HBr /  
Cough Suppressant  
Doxylamine Succinate /  
Antihistamine

**Cold & Flu**

Cherry Flavor

ALCOHOL 10%

Relief of:

- Pain
- Fever
- Cough
- Sneezing
- Runny Nose



12 FL OZ (355 mL)

: 45940 1J F6

MADE WITH  
PRIDE & CARE FOR H-E-B®  
SAN ANTONIO, TX 78204

100% GUARANTEE  
promise

GLUTEN  
FREE

DO NOT USE IF PRINTED NECKBAND IS  
BROKEN OR MISSING

28190-2203

## PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

Drug Facts	
Active ingredients	Purpose
<i>(in each 30 mL)</i>	
Acetaminophen	Pain reliever/ fever reducer
650 mg.....	
Dextromethorphan HBr	
30 mg.....	Cough suppressant
Doxylamine succinate	
12.5 mg.....	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.

PEEL BACK AT  
CORNER FOR MORE  
INFORMATION

: 45940 1J B1



### Drug Facts (continued)

**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.

**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

ADHESIVE AREA  
NO VARNISH • NO TYPE

### Drug Facts (continued)

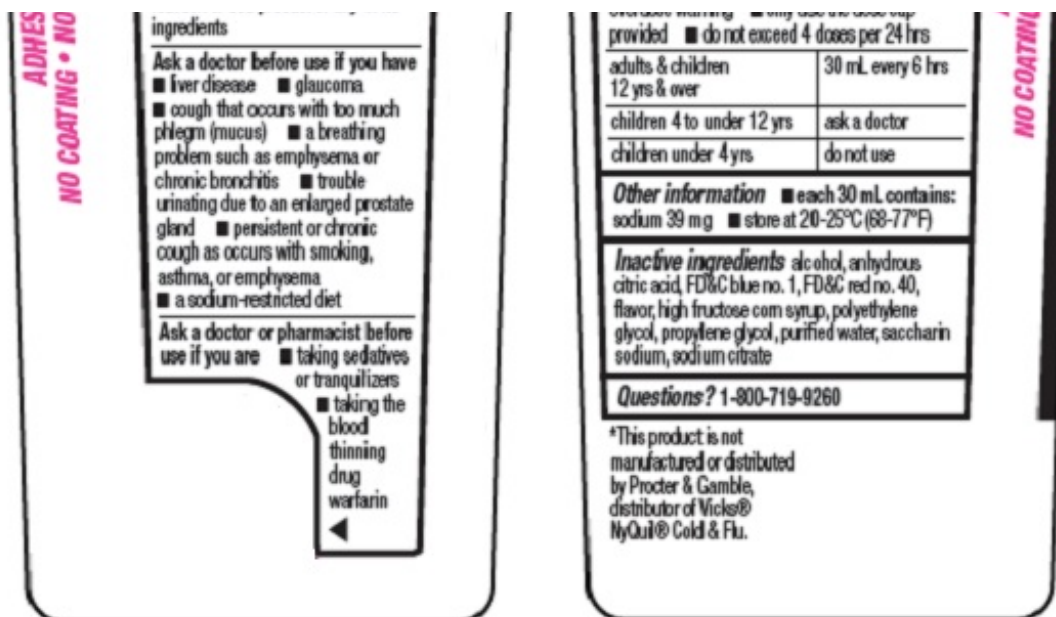
When using this product  excitability  
 may occur, especially in children  marked  
 drowsiness may occur  avoid alcoholic drinks  
 be careful when driving a motor vehicle or operating  
 machinery  alcohol, sedatives, and tranquilizers  
 may increase drowsiness

**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  only use the dose cup

ADHESIVE AREA  
NO VARNISH • NO TYPE



## NIGHT TIME

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-459
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB65)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

## Product Characteristics

<b>Color</b>	RED (Clear/Dark Red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY (Menthol Aroma)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-459-38	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2012	04/28/2014
2	NDC:37808-459-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2012	
3	NDC:37808-459-50	2 in 1 PACKAGE	07/20/2012	01/31/2020
3		355 mL in 1 BOTTLE; 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	02/04/2012	

**Labeler** - H E B (007924756)

Revised: 2/2023

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