# DAY TIME NIGHT TIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl 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.

-----

### **HEB DayTime NightTime Severe Cold & Flu Drug Facts**

## Nighttime Severe Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Doxylamine succinate 12.5 mg
Phenylephrine HCl 10 mg

### **Purpose**

Pain reliever/fever reducer Cough suppressant Antihistamine Nasal decongestant

### Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

# 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 such 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

- 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, and tranquilizers may increase drowsiness

### Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, 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 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- each 30 mL contains: sodium 41 mg
- store at 20-25°C (68-77°F)

# **Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

### **Questions or comments?**

### 1-800-719-9260

# Daytime Severe Cold & Flu Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCI 5 mg

### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

### Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- · promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

# **Warnings**

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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 gets worse or lasts more than 5 days (children) or 7 days (adults)
- 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 care 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 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

### Other information

- each 15 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

# **Inactive ingredients**

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

### Questions or comments?

1-800-719-9260

# **Principal Display Panel**

Combo Pack

Daytime & Nighttime Relief

Compare to Vicks® DayQuil® Severe and NyQuil® Severe active ingredients

Compare to Vicks® DayQuil® Severe active ingredients

H-E-B<sub>®</sub> Maximum Strength Daytime **SEVERE** Acetaminophen Pain Reliever / Fever Reducer

Phenylephrine HCI / Nasal Decongestant

Dextromethorphan HBr / Cough Suppressant

Guaifenesin / Expectorant

Cold & Flu

Non-Drowsy

Alcohol Free

Relief of:

- Pain Fever Cough
- Nasal Congestion

12 FL OZ (355 mL) (Day)

Compare to Vicks® NyQuil® Severe active ingredients

H-E-B<sub>®</sub>

Maximum Strength

Nighttime

**SEVERE** 

Acetaminophen

Pain Reliever / Fever Reducer

Phenylephrine HCl / Nasal Decongestant

Doxylamine Succinate / Antihistamine

Dextromethorphan HBr / Cough Suppressant

Cold & Flu

Berry Flavor

Alcohol Free

Relief of:

- Pain Fever Cough
- Sneezing
   Runny Nose

12 FL OZ (355 mL) (Night)





**Combo Pack** N DC 37808-597-02 **Daytime & Nighttime Relief** 

Compare to Vicks® DayQuil® Severe and NyQull® Severe active ingredients\*

DayQuil J. MPARE TO Compare to Vicks<sup>a</sup> DayQuil<sup>a</sup>Severe active ingredients' H-E-B Maximum Strength Acetaminophen Pain Reliever / Fever Reducer Phenylephrine HCI / Nasal Decongestant Dextromethorphan HBr / Cough Suppressant Guaifenesin / Expectorant

Cold & Flu

Pain • Fever • CoughNasal Congestion

Non-Drowsy

Alcohol Free

Relief of:

NYQu. COMPARE TO Compare to Vicks® NyQuil® Severe active ingredients H-E-B **Maximum Strength** ighttime Acetaminophen Pain Reliever / Fever Reducer Phenylephrine HCI / Nasal Decongestant Doxylamine Succinate / Antihistamine Dextromethorphan HBr / Cough Suppressant

Learn about teen medicine abuse

\*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks ® DayQuil® Severe and NyQuil® Severe.

Cold & Flu

Berry Flavor

- Relief of:
   Pain Fever Cough
   Sneezing Runny Nose

12 FL OZ (355 mL) (Night)

12 FL OZ (355 mL) (Day)



PARENTS:

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

www.StopMedicineAbuse.org

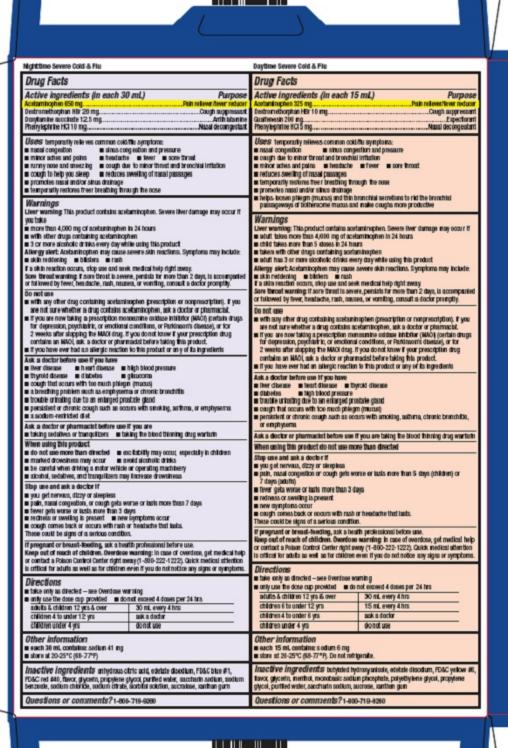
**GLUTEN FREE** 

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

Alcohol Free



59702 1J C5



### DAY TIME NIGHT TIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-597

### **Packaging**

ı		rackaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date		
		NDC:37808-597- 02	1 in 1 PACKAGE; Type 0: Not a Combination Product	04/14/2016		

### **Ouantity of Parts**

4 0.0	quantity of the control of the contr			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE	355 mL		
Part 2	1 BOTTLE	355 mL		

### Part 1 of 2

### NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl solution

### **Product Information**

 Item Code (Source)
 NDC:37808-763

 Route of Administration
 ORAL

### **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength 650 mg ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) | ACETAMINOPHEN in 30 mL **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) DEXTROMETHORPHAN 20 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 30 mL DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE -12.5 mg DOXYLAMINE SUCCINATE UNII:95QB77JKPL) in 30 mL PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -**PHENYLEPHRINE** 10 mg **HYDROCHLORIDE** UNII:1WS297W6MV) in 30 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics				
Color	RED (clear, dark)	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:37808-763- 40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC monograph final	part341	04/11/2016		

# Part 2 of 2

# **DAYTIME SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

<b>Product Information</b>	
Item Code (Source)	NDC:37808-603
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL	

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics				
Color	ORANGE (clear)	Score		
Shape		Size		
Flavor	FRUIT, MENTHOL	Imprint Code		
Contains				

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1	NDC:37808-603- 40	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	04/11/2016			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	04/14/2016			

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

Revised: 6/2023 H E B