# FOSTER AND THRIVE NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate solution Strategic Sourcing Services LLC

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# McKesson Nighttime Cold & Flu Relief 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
- use dose cup
- do not exceed 4 doses per 24 hrs

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

#### Other information

- each 30 mL contains: sodium 38 mg
- store at 20-25°C (68-77°F)

## **Inactive ingredients**

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

## Questions or comments?

Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

# Package/Label Principal Display Panel

COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS

Foster & Thrive™

**NIGHTTIME** 

Cold & Flu Relief

Acetaminophen

Dextromethorphan HBr

Doxylamine Succinate

Pain Reliever

Fever Reducer Cough Suppressant **Antihistamine** Gluten Free ALCOHOL 10% ORIGINAL FLAVOR 8 FL OZ (237 mL)



#### Drug Facts (continued)

#### Do not use

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- 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.
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1033
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			

Product Characteristics			
Color	GREEN (clear, bright green)	Score	
Shape		Size	
Flavor	FRUIT (anise / cooling menthol aroma)	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677- 1033-1	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2023	
2	NDC:70677- 1033-2	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/17/2023	

**Labeler -** Strategic Sourcing Services LLC (116956644)

Revised: 10/2023 Strategic Sourcing Services LLC