DAY TIME- acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid HyVee Inc

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.

Hy-Vee, Inc. Day Time Cold & Flu Drug Facts

Active ingredient (in each 15 ml tablespoon)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. 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, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is 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 as occurs with smoking, asthma, 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.

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 Liver warning
- use dose cup
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 ml (2 TBSP) every 4 hrs
children 6 to under 12 yrs	15 ml (1 TBSP) every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

 when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each tablespoon contains: sodium 7 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 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

Compare to Vicks® DayQuil® active ingredients

Day Time Cold & Flu

Non-Drowsy

Multi-Symptom Relief

Acetaminophen – Aches, Fever

Dextromethorphan HBr - Cough

Phenylephrine HCl – Nasal Congestion

ALCOHOL FREE

ANTIHISTAMINE FREE

Pain Reliever, Fever Reducer, Cough Suppressant, Nasal Decongestant





Cough Suppressant, Nasal Decongestant

(355 ml)

Drug Facts Do not use if printed neckband is broken or missing Active ingredients (in each 15 ml tablespoon) Acetaminophen 325 mg.....Pain Dextromethorphan HBr 10 mg.....Pain reliever/fever reducer .Cough suppressant nenylephrine HCl 5 mg..... Nasal decongestant Uses temporarily relieves common cold/flu symptoms: ■ headache sore throat minor aches and pains nasal congestion cough due to minor throat and bronchial irritation Warnings Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. 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, which is the maximum daily amount taken with other drugs containing acetaminophen adult has 3 or more alcoholic drinks every day while using this product Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is 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 contain acetaminophen, ask a doctor or pharmacist.

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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 ■ diabetes ■ thyroid disease ■ high blood pressure ■ heart disease ■ trouble urinating due to an enlarged prostate gland persistent or

cough that occurs with too much phlegm (mucus)
 persi chronic cough as occurs with smoking, asthma, 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

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DAY TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42507-656
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	325 mg in 15 mL		
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
PHENYLEPHRINE HYDRO CHLO RIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLATED HYDRO XYANISOLE			
EDETATE DISO DIUM			
FD&C YELLOW NO. 6			
GLYCERIN			
MENTHO L			
SO DIUM PHO SPHATE, MO NO BASIC			
POLYETHYLENE GLYCOLS			
PROPYLENE GLYCOL			
WATER			
SACCHARIN SO DIUM			

SUCROSE	
XANTHAN GUM	

Product Characteristics			
Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42507-656-30	177 mL in 1 BOTTLE			
2	NDC:42507-656-38	296 mL in 1 BOTTLE			
3	NDC:42507-656-40	355 mL in 1 BOTTLE			
4	NDC:42507-656-34	237 mL in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/11/2006	

Labeler - HyVee Inc (006925671)

Revised: 3/2013 HyVee Inc