DAYTIME COLD AND FLU- acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled

Mckesson

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.

Acetaminophen, Dextromethorphan and Phenylephrine Day time Cold and Flu

Active Ingredient

(in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

pain reliever Cough Suppressant Nasal decongestant

Uses

pain reliever, cough suppressant and Nasal decongestant

Warnings

Warnings Failure to follow these warnings could result in serious consequences.

Liver Warning: This product contains <u>acetaminophen</u>. Severe liver damage may occur if you take

- more than 4 doses in 24 hours which is maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

do not use:

- with any other drug containing <u>acetaminophen</u> (prescription or not prescription). 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.

Ask a doctor before use if you have

- liver disease
- Heart disease
- Thyroid disease
- Diabetes
- High blood pressure
- Trouble urinating due to enlarged prostate gland

ask your 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:

- Redness or swelling is present
- You get nervous, dizzy or sleepless
- Fever gets worse or lasts more than 3 days
- New symptoms occur
- Symptoms do not get better within 7 days or are accompanied by a fever

Keep out of reach of children.

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning: Taking more than recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Tamper evident: this package is safety sealed and child resistant. Use only if blisters are intact. If difficult to open use scissors.

Direction

- do not exceed 4 doses per 24 hours
- take only as directed see overdose warning
- Adults and children 12 years and over: 2 softgels with water every 4 hours
- Children under 4 to under 12 years: ask a doctor
- Children under 4 years: do not use

Other Information

• store at room temperature

Inactive Ingredients

FD&C Red No.40, FD&C Yellow No. 6, Gelatin, Glycerin, Poyethylene Glycol, Povidone, Propylene Glycol, Purified Water, Sorbitol Special, Titanium dioxide

Questions or Comments

Call toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Please visit us at www.healthmart.com/healthmarthrand Money Back Guarantee One Post Street, San Francisco, CA 94104 Distributed By McKesson Another Quality Product

WEKE220N



idniq cabs

ACTUAL SIZE

multi-symptom • cold & flu relief

alcohol free • antihistamine-free condy suppressant decongestant pain reliever/fever reducer

Dhenylephine HCI

acetaminophen/dextromethorpan HBr

day time liq

liquid caps active ingredients* compare to Vicks® Day Quil®





Health Mart

NDC 62011-0318-1

Drug Facts

Active ingredients (in each softgel) Purpose

....Pain reliever Fever reducer ng Cough suppressantNasal decongestant Aceterminophen 325 mg....... Pain r Deut romethorphan HBr 10 mg...... Phenylephrine HCl 5 mg......

Directions

■ Do not exceed 4 doses per 24 hours.

■ Take only as directed - see Overdose warning

Adults and Children

12 years and over

■ 2 sottgels with
water every 4 h 2 softgels with water every 4 hours

Children 4 to under 12 years | mask a dockr

Children under 4 years m do not use Inactive ingredients: FD&C Re No.40, FD&C Yellow No. &, Gelatin, Glyceln, Polyethylene Glycol, Povidone, Propylene, Glycol, Purified Water, Sorbitol Special, Titanium Dicoide

Other Information: Store at room temperature

Questions? call: 1-855-314-1850

Drug Facts (continued)

Uses: temporarily relieves common cold/flu symptoms:

massi congestion moough due to minor throat & bronchial irritation m sore throat m he adache m minor aches & pains m lever

Warnings: Failure to follow these warnings could result in serious consequences.

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

More than 4 doses in 24 hours, which is the maximum daily amount for this product

With other drugs containing acetaminophen

3 or more alcoholic drinks daily while using this product

Allergy alert: acetaminophen may cause severe skin reactions, symptoms may include: # skin reddering #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.

with any other drug containing acetaminophen, (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist, m If you are now taking a prescription monoemine oddase 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 advance of the product of the produ contains an MACI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have: _m Liver disease _m Heart disease _m Thyroid disease _m Diabetes _m High blood pressure _m Trouble urinating due to enlarged prostate gland _m cough that occurs with too much philegm (mucus) _m Persistent or chronic cough such as occurs with smoking, asthma, or emphysema

As k a doctor or pharmac ist before use if you are taking the blood-thinning drug warfar in.

When using this product, do not use more than directed.

Step use and ask a doctor if: __Rechess or swelling is present __You get nervous, dizzy, or sleepless __New symptoms occur ___Rever gets worse or last more than 3 days ___ pain, nasal congestion or cough get worse or last more than 7 days for a nadult or 5 days for a child 12 years or older ___ cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.

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If pregnant or breast-feeding: ask a health professional before use. Keep out of reach of children.

Overdose warning: Taking more than the recommended dose can cause serious health problems, in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

NDC: 62011-0318-1 24 liquid caps

DAYTIME COLD AND FLU

acetaminophen,dextromethorphan,phenylephrine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0318

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)		
POVIDONE (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	512
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62011-0318-1	24 in 1 BLISTER PACK	11/25/2016	
1	1 in 1 CARTON; 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	11/25/2016	

Labeler - Mckesson (177667227)

Registrant - Velocity Pharma (962198409)

Revised: 12/2016 Mckesson