# DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hbr and phenylephrine hcl 325 mg, 10 mg and 5 mg capsule, liquid filled We Care Distributor 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.

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## DAYTIME COLD & FLU - Acetaminophen, Dextromethorphan HBr and Phenylephrine HCl *Drug Facts*

Active Ingredient (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	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. 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

## 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 monomine 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
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)

## 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 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- 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 (1-800-222-1222) right away. 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
- do not exceed 6 doses per 24 hours
- adults and children 12 years and over: 2 softgels with water every 4 hours
- children 4 to under 12 years: ask a doctor
- children under 4 years: do not use
- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

## Other information

- store at 20°-25°C (68°-77°F)
- read all product information before using. Keep this box for important information

## Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, methylparaben, polyethylene glycol, povidone, propylene glycol, propylparaben, purified water, sorbitol solution, titanium dioxide

#### Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

## PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

#### Compare to the Active Ingredients in

DayQuil® LiquiCaps®

#### Acetaminophen, Dextromethorphan HBr and Phenylephrine HCl 325 mg, 10 mg and 5 mg

#### TO OPEN PUSH IN TAB AND PULL OUT

#### 25 Pouches of 2 Softgels Each



## DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr and phenylephrine hcl 325 mg, 10 mg and 5 mg capsule, liquid filled

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source) NDC:70005-003		5-003	
Route of Administration	ORAL				
Active Ingredient/Active Mo	iety				
•	iety redient Name		Basis of St	rength	Strength
<b>U</b>	redient Name	5209 ITL9 D)	Basis of St ACETAMINOPHEN	0	Strength 325 mg

	Inactive Ingredients					
Ingredient Name				Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)           FD&C YELLOW NO. 6 (UNII: H77VEI93A8)						
GELATIN (UNII: 2G860						
GLYCERIN (UNII: PDC)						
METHYLPARABEN (U						
POLYETHYLENE GLY POVIDONE (UNII: FZ9)			1)			
PROPYLENE GLYCOI						
PROPYLPARABEN (UNII: Z8IX2SC10H)         WATER (UNII: 059QF0K00R)						
SORBITOL (UNII: 506T60A25R)						
TITANIUM DIO XIDE (						
(	51111. 1511					
Product Characte	ristics					
Color		orange	Score	r	io score	
Shape		OVAL	Size	22mm		
Flavor			Imprint Code	SN;2		
Contains			<b>1</b>			
Packaging						
Packaging # Item Code		Package Desc	ription	Marketing Start Date	Marketing End Date	
# Item Code	25 in 1 l	Package Desc	ription	Marketing Start Date	Marketing End Date	
# Item Code		BOX	-	Marketing Start Date	Marketing End Date	
#         Item Code           1         NDC:70005-003-25		BOX DUCH; Type 0: Not a C	-	Marketing Start Date	Marketing End Date	
Item Code           NDC:70005-003-25           I	2 in 1 PC	BOX OUCH; Type 0: Not a C BOX	ombination Product	Marketing Start Date	Marketing End Date	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/15/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Softech Pharma Pvt. Ltd		677111277	manufacture(70005-003)		

Revised: 2/2016