

D - TIME- acetaminophen, phenylephrine hydrochloride, and dextromethorphan hydrobromide capsule, liquid filled
SPIRIT PHARMACEUTICALS,LLC

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.

D-Time Soft Gelatin Capsules

Drug Facts

Active ingredients (in each LiquiCap)	Purpose
Acetaminophen 325mg	Pain reliever/Fever Reducer
Dextromethorphan Hbr 10mg	Cough Suppressant
Phenylephrine HCl 5 mg	Nasal Decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

Alcohol Warnings :if you consume 3 or more alcoholic drinks every day, ask you doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Sore throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever,headache,rash,nausea or vomiting, consult a doctor promptly.

Do not use

- **with other medicines containing acetaminophen**
- 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

- heart disease
- thyroid disease
- Diabetes
- high blood pressure
- trouble urinating due to enlarged postage gland
- cough that occurs with too much phlegm(mucus)
- persistent or chronic cough as occurs with smoking, asthma or emphyesma

when using this product do not use more than directed

Stop use and ask doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- fever gets worse or less 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 conditions

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 as well as for children even if you do not notice any signs or symptoms.

Direction

- take only as recommended – see Overdose warning
- do not exceed 6 doses per 24 Hours

adults and children 12 years of age and older	-2 liquicaps with water every 4 hours
children under 12 years of age	- ask a doctor

Other information

- **each tablet contains** : Store at room temperature

Inactive ingredients

FD &C Red No 40 IH, Polyethylene Glycol 400, Gelatin, Glycerin, Povidone, Purified water, Sorbitol

PRINCIPAL DISPLAY PANEL - 6000 Capsules Label

D-Time Soft Gelatin Capsules

Each soft gelatin capsule contains :

Acetaminophen USP	325 mg
Phenylephrine Hydrochloride USP	5 mg
Dextromethorphan Hydrobromide USP	10 mg

LOT NO :	NDC NO : 68210-1490-6
MFG DATE :	QUANTITY : 1000 X 6 Softgels
EXP. DATE :	GROSS WT. :

WARNING:

KEEP OUT OF REACH OF CHILDREN

**STORE AT CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30 °C)
 PROTECT FROM LIGHT, MOISTURE AND FREEZING**

**THIS BULK SHIPMENT IS INTENDED FOR FURTHER PACKAGING PROCESS ONLY.
 CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT
 CONFORMANCE WITH THE FD & C ACT AND REGULATIONS THEREUNDER.**

**MANUFACTURED BY:
 Marksans Pharma Ltd
 VERNA, GOA-403722,
 INDIA.
 CODE : GO/DRUGS/515**

**MANUFACTURED FOR:
 SPIRIT PHARMACEUTICALS LLC
 225 LINCOLN HWY, STE 205
 FAIRLESS HILLS, PA 19030
 PH.# 215 943 4000
 FAX.# 215 943 4039**

**CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"
 OGIL056**

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D - TIME

acetaminophen, phenylephrine hydrochloride, and dextromethorphan hydrobromide capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1490
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1490-5	1 in 1 DRUM		
1		5000 in 1 BAG		
2	NDC:68210-1490-6	1 in 1 DRUM		
2		6000 in 1 BAG		
3	NDC:68210-1490-4	1 in 1 DRUM		
3		4000 in 1 BAG		
4	NDC:68210-1490-8	1 in 1 DRUM		
4		8000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/30/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 7/2010

SPIRIT PHARMACEUTICALS,LLC