ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, AND PHENYLEPHRINE HYDROCHLORIDE - acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride 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.

Acetaminophen, Dextromethorpan HBr & Phenylephrine HCL capsule

Drug Facts

Active ingredients (in each LiquiCap)	***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

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your 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 prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

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

Stop use and ask a 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 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: 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.

Directions

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

adults and children 12 years and over	2 LiquiCaps with water every 4 hours
children under 12 years	ask a doctor

- **when using other DayQuil or NyQuil products, carefully read each label to insure correct dosing**

Other information

- store at room temperature

Inactive ingredients

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

Questions?

1-800-251-3374

PRINCIPAL DISPLAY PANEL

Acetaminophen, Dextromethorphan HBr Phenylephrine HCL capsules

Each Softgel Contains:
(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg,
Phenylephrine Hydrochloride USP 5mg)

LOT NO:
DRUM NO:
MFG DATE:
QUANTITY:

NDC NO: 68210-0101-
EXP DATE:

WARNING:
KEEP OUT OF REACH OF CHILDREN

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

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH
THE F.D & C.ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:
SOFTGEL HEALTHCARE PVT LIMITED
INDIA
LABELLER CODE: 35916
LIC NO.: TN/DRUGS/00002124

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"

- 1 – 4
- 2 – 100
- 3 – 1000
- 4 – 5000
- 5 – 10000
  6 - 2500

Acetaminophen, Dextromethorphan HBr Phenylephrine HCL capsules

Each Softgel Contains:
(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg,
Phenylephrine Hydrochloride USP 5mg)

LOT NO :
DRUM NO :
MFG DATE :
QUANTITY :
NDC NO : 68210-0101-
EXP DATE :

WARNING:
KEEP OUT OF REACH OF CHILDREN

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

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C.ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:
SOFTGEL HEALTHCARE PVT LIMITED
INDIA
LABELLER CODE : 35916
LIC NO. : TN/DRUGS/00002124

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"

- 1 – 4
- 2 – 100
- 3 – 1000
- 4 – 5000
- 5 – 10000

6 - 2500

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, AND PHENYLEPHRINE HYDROCHLORIDE

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	

GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics			
Color	ORANGE	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0101-1	4 in 1 BOX		
2	NDC:68210-0101-2	100 in 1 BOX		
3	NDC:68210-0101-3	1000 in 1 BOX		
4	NDC:68210-0101-4	5000 in 1 BOX		
5	NDC:68210-0101-5	10000 in 1 BOX		
6	NDC:68210-0101-6	2500 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/15/2009	

Labeler - SPIRIT PHARMACEUTICALS, LLC (179621011)

Revised: 9/2010 SPIRIT PHARMACEUTICALS, LLC