ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, AND DOXYLAMINE SUCCINATE- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate 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 & Doxylamine Succinate capsule

Drug Facts

Active ingredients (in each LiquiCap)	*Purpose*
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

temporarily relieves common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- 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 4 doses per 24 hours

adults and children 12 years and over	2 LiquiCaps with water every 6 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

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, titanium dioxide

PRINCIPAL DISPLAY PANEL

Acetaminophen, Dextromethorphan HBr & Doxylamine Succinate capsule

Each Softgel Contains:
(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg,
Doxylamine Succinate USP 6.25mg)

LOT NO:
DRUM NO:

MFG DATE:
QUANTITY:
NDC NO: 68210-0102-
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

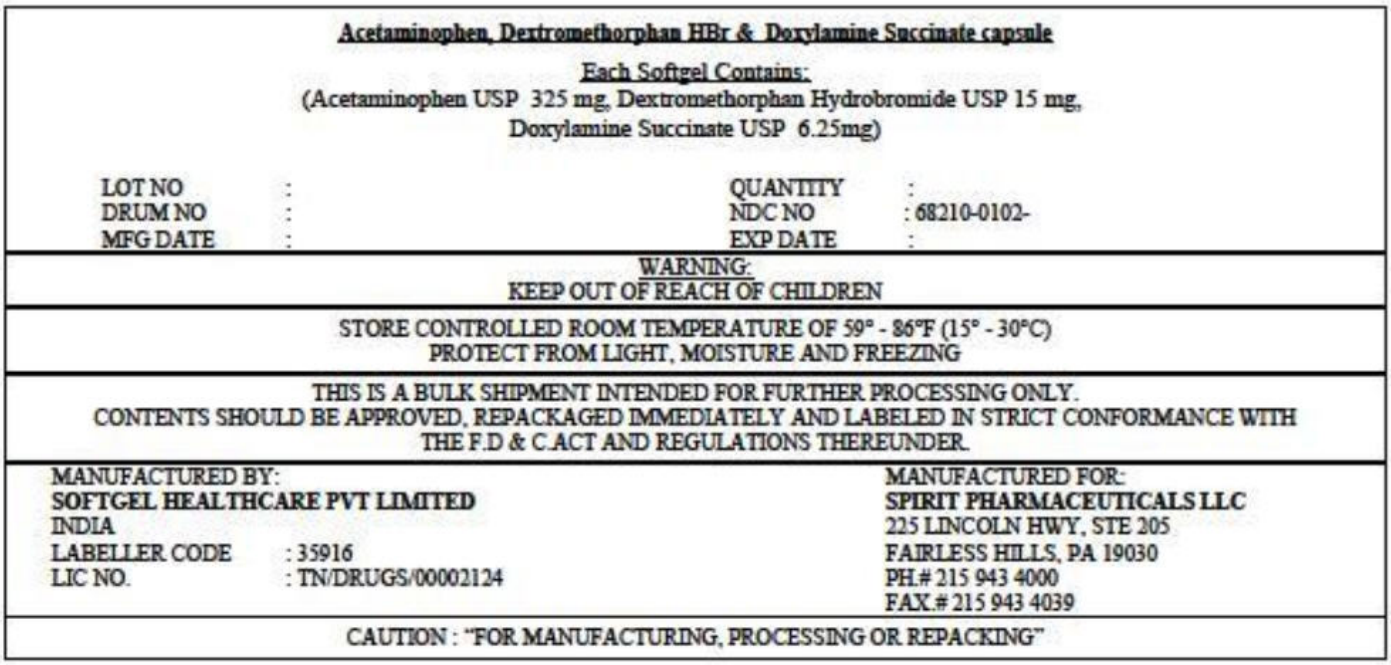
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH
THE F.D & C.ACT AND REGULATIONS THEREUNDER.

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



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ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, AND DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0102
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 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	GREEN	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0102-1	4 in 1 BOX		
2	NDC:68210-0102-2	100 in 1 BOX		
3	NDC:68210-0102-3	1000 in 1 BOX		
4	NDC:68210-0102-4	5000 in 1 BOX		
5	NDC:68210-0102-5	10000 in 1 BOX		
6	NDC:68210-0102-6	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