N - TIME SINUS- acetaminophen, doxylamine succinate, 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.

N-Time Sinus Soft Gelatin Capsules

Drug Facts

Active ingredients for NyQuil Sinus (in each LiquiCap)	***Purpose***
Acetaminophen 325 mg	Pain reliever
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves nasal and sinus symptoms:

- sinus pain
- headache
- nasal and sinus congestion
- runny nose and sneezing (NyQuil Sinus only)

Warnings

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

- more than 6 doses in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkison'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.
- to make a child sleep

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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

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

When using these products

- **do not use more than directed**

In addition, when using NyQuil Sinus:

- 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

- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- you get nervous, dizzy or sleepless
- fever gets worse or lasts more than 3 days
- new symptoms occur

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

NyQuil Sinus OR **DayQuil Sinus**

adults and children 12 years and over	2 LiquiCaps with water every 4 hours
children 2 to under 12 years	ask a doctor
children under 2 years	do not use

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

Other information

- store at room temperature

Inactive ingredients

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

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

PRINCIPAL DISPLAY PANEL - 6000 Softgel Label

N-Time Sinus Soft Gelatin Capsules

Each Softgel Contains:
Acetaminophen USP 325mg
Doxylamine Succinate USP 6.25mg
Phenylephrine HCL USP 5mg

LOT NO :	NDC NO : 68210-1480-6
MFG DATE :	QUANTITY : 6000 Softgels
EXP DATE :	GROSS WT. :

WARNING:
KEEP OUT OF REACH OF CHILDREN

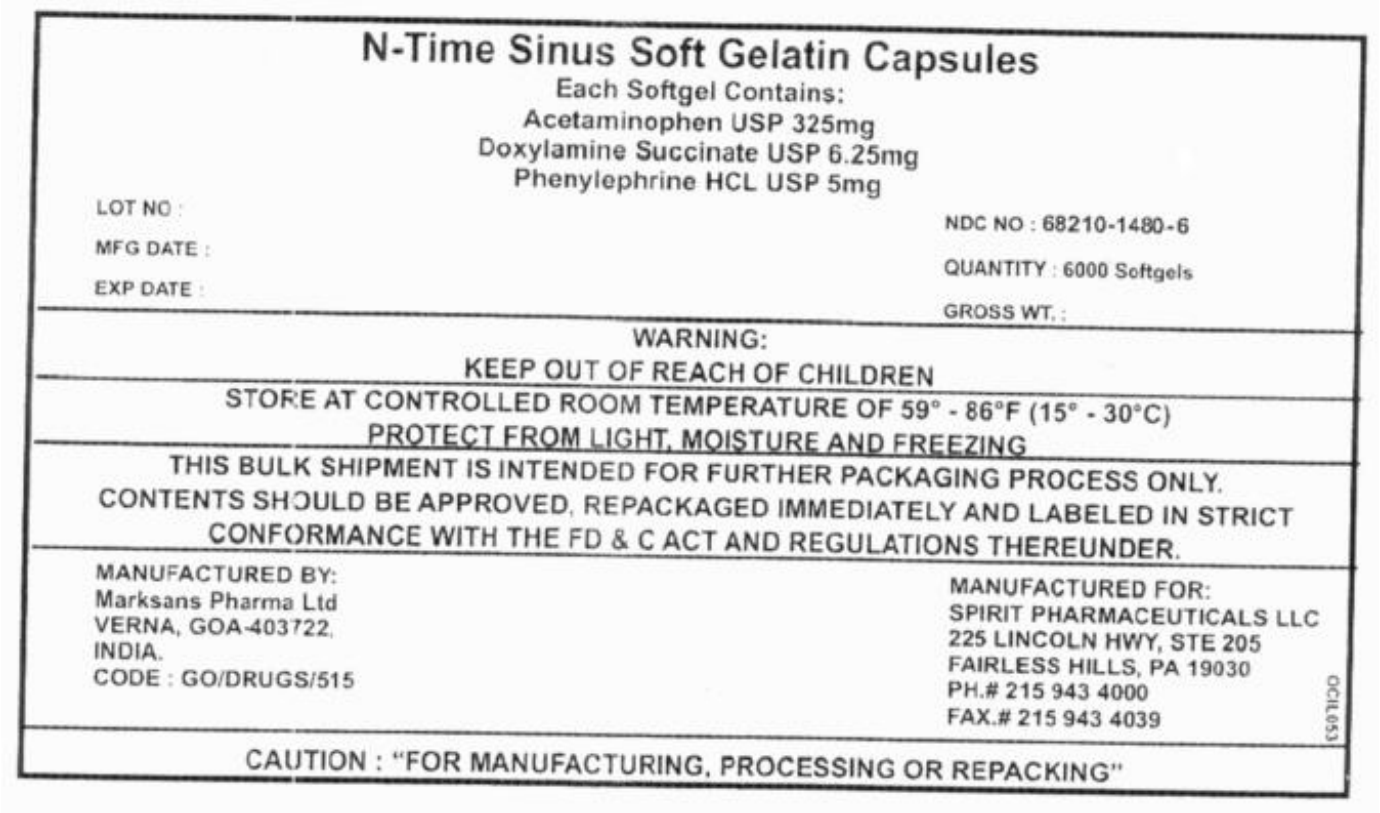
STORE AT CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

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"



N - TIME SINUS

acetaminophen, doxylamine succinate, and phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-1480
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE Hydrochloride (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE Hydrochloride	5 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: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	130
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1480-5	5000 in 1 DRUM		
2	NDC:68210-1480-6	6000 in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/01/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 7/2010 SPIRIT PHARMACEUTICALS,LLC