NIGHT TIME SINUS AND CONGESTION- acetaminophen, doxylamine succinate, phenylephrine hcl capsule, liquid filled
Chain Drug Consortium, 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.

Drug Facts

Active ingredient(s)

Acetaminophen 325 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/Fever reducer

Antihistamine

Nasal decongestion

Uses

- temporarily relieves symptoms due to common cold
- minor aches and pains
- headache
- fever
- runny nose and sneezing
- nasal congestion
- sinus congestion & pressure
- temporarily relieves symptoms due to hay fever or other upper respiratory allergies
- minor aches and pains
- headache
- runny nose and sneezing
- itching of the nose or throat, and itchy, watery eyes
- nasal congestion
- sinus congestion & pressure

Warnings

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- 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). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- 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.
- to make a child sleep

Ask a doctor before use if

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use ifyou are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

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 & tranquilizers may increase drowsiness

Stop use and ask doctor if

- pain or nasal congestion 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
- you get nervous, dizzy or sleepless

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 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**
- take only as directed

adults & children 12 years & over	2 Liquid Caps with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- store at controlled room temperature 15°C to 30°C (59°F to 86°F)

Inactive ingredients

edible white ink, FD&C Blue No. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sorbitol

Questions or comments?

1-800-706-5575

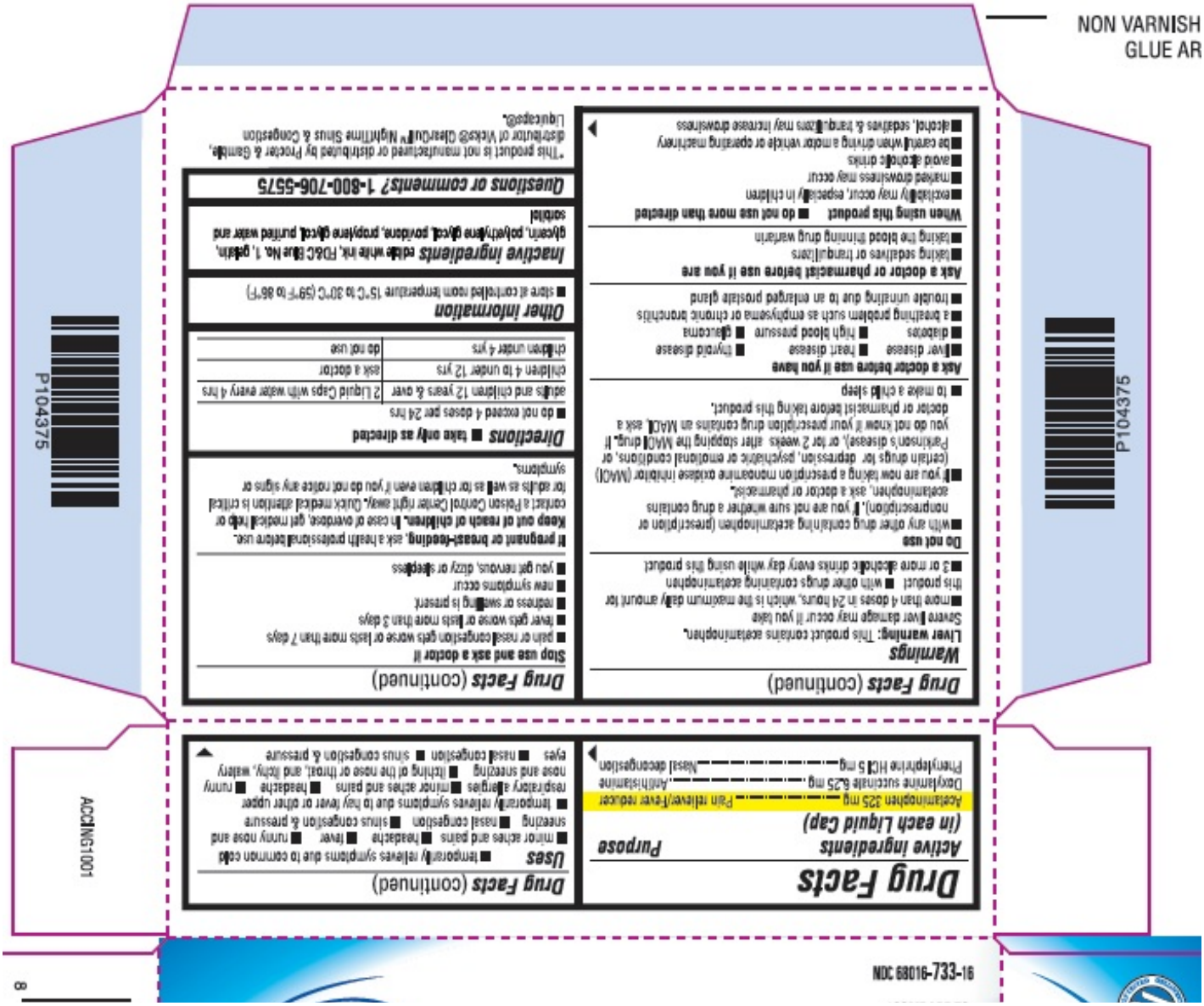
Principal Display Panel

Premier Value

Nighttime Sinus and Congestion

NDC number 68016-733-16

16 Liquid Capsule



NIGHT TIME SINUS AND CONGESTION

acetaminophen, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-733
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE K12 (UNII: 333AG72FWJ)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	16mm
Flavor		**Imprint Code**	47A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-733-16	8 in 1 BLISTER PACK		
1		2 in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/12/2015	

Labeler - Chain Drug Consortium, LLC (101668460)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Limited		248441727	analysis(68016-733) , manufacture(68016-733)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Limited Strathroy		243944050	analysis(68016-733) , manufacture(68016-733)

Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging		969852743	pack(68016-733)

Revised: 10/2015 Chain Drug Consortium, LLC