

SINUS RELIEF DAYTIME NIGHTTIME- acetaminophen, doxylamine succinate, phenylephrine hcl

WALGREEN CO.

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.

Walgreens 44-553554

Active ingredients (in each liquid cap)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Nasal decongestant

Uses

- temporarily relieves nasal and sinus symptoms:
 - sinus pain
 - headache
 - nasal and sinus congestion

Warnings

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

- more than 12 liquid caps in 24 hours, which is the maximum daily amount
- 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin

When using this product

- do not exceed recommended dosage

Stop use and ask a doctor if

- redness or swelling is present
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

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 (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quickmedical 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)
- adults and children 12 years and over
 - 2 liquid caps with water every 4 hours
 - do not take more than 12 liquid caps in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number
- for better identification, keep liquid caps in carton until used

Inactive ingredients

edible white ink, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Active ingredient (in each liquid cap)

Acetaminophen 325 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves nasal and sinus symptoms:
 - headache
 - sinus pain
 - nasal and sinus congestion
 - runny nose and sneezing

Warnings

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

- more than 12 liquid caps in 24 hours, which is the maximum daily amount
- 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.

Ask a doctor before use if

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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

When using this product

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

Stop use and ask a doctor if

- redness or swelling is present
- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur

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 (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quickmedical 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)**
- adults and children 12 years and over
 - 2 liquid caps with water every 4 hours
 - do not take more than 12 liquid caps in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number
- for better identification, keep liquid caps in carton until used

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal Display Panel

COMBO PACK

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED

NDC 0363-0555-22

NON-DROWSY • DAYTIME

Sinus Relief

Acetaminophen /

Sinus Headache & Pain

Phenylephrine HCl /

Sinus Pressure

& Congestion

32 LIQUID CAPS

NGHTTIME

Sinus Relief

Acetaminophen /

Sinus Headache & Pain

Doxylamine Succinate /

Runny Nose

Phenylephrine HCl /

Sinus Pressure & Congestion

16 LIQUID CAPS

Compare to Vicks® DayQuil® & NyQuil® Sinex® Sinus Relief LiquiCaps® active ingredients

48 TOTAL LIQUID CAPS

Walgreens Pharmacist Survey Study, November 2010

This product is not manufactured or distributed by Novartis Consumer Health, owner of the registered trademark Excedrin® Extra Strength Tablets.

50844 REV1012.553/554A22

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS
TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

SINUS RELIEF DAYTIME NIGHTTIME

acetaminophen, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0555
--------------	----------------	--------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0555-22	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32 in 4
Part 2	2 BLISTER PACK	16 in 2

Part 1 of 2

NON DROWSY DAYTIME SINUS RELIEF

acetaminophen, phenylephrine hcl capsule

Product Information

Item Code (Source)	NDC:0363-0000
--------------------	---------------

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

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm

Flavor	MINT	Imprint Code	48A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/15/2005	

Part 2 of 2

NIGHTTIME SINUS RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

Item Code (Source)	NDC:0363-0009
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor	MINT	Imprint Code	47A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/21/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/21/2005	

Labeler - WALGREEN CO. (008965063)**Establishment**

Name	Address	ID/FEI	Business Operations
Accucaps Industries, Ltd.		248441727	MANUFACTURE(0363-0555, 0363-0000, 0363-0009)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0555, 0363-0000, 0363-0009)

Revised: 2/2013

WALGREEN CO.