

## **SINUS CONGESTION AND PAIN RELIEF NON-DROWSY, DAYTIME- acetaminophen and phenylephrine hcl tablet**

**Rite Aid Corporation**

*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.*

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**Rite Aid 44-558**

### ***Active ingredients (in each gelcap)***

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

### ***Purpose***

Pain reliever/fever reducer

Nasal decongestant

### ***Uses***

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - headache
  - sinus congestion and pressure
  - minor aches and pains
  - nasal congestion
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages
- temporarily reduces fever

### ***Warnings***

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

### ***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.

- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have**

- liver disease
- thyroid disease
- heart disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure

**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**

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

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.**

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

***Directions***

- **do not take more than directed**
- adults and children 12 years and over
- take 2 gelcaps every 4 hours
- do not take more than 12 gelcaps in 24 hours
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- avoid high humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, croscarmellose sodium, crospovidone, D&C yellow #10, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, shellac glaze, silicon dioxide, stearic acid, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

***Principal Display Panel***

**RITE AID®  
PHARMACY**

\*Compare to the active ingredients in Tylenol® SINUS + HEADACHE Day

**sinus congestion  
& pain relief**

**acetaminophen** 325 mg  
phenylephrine HCl 5 mg  
pain reliever/fever reducer  
nasal decongestant

***NON-DROWSY  
DAYTIME***

relieves:  
headache  
nasal congestion  
sinus congestion & pressure

**ACTUAL SIZE**

**RAPID RELEASE  
2 GELCAPS**

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

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® SINUS + HEADACHE Day.

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**DISTRIBUTED BY:  
RITE AID  
30 HUNTER LANE  
CAMP HILL, PA 17011**

**SATISFACTION RITE AID GUARANTEE  
IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.**

## SINUS CONGESTION AND PAIN RELIEF NON-DROWSY, DAYTIME

acetaminophen and phenylephrine hcl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0588
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CROSPVIDONE (UNII: 2S7830E561)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POVIDONE (UNII: FZ989GH94E)			
SHELLAC (UNII: 46N107B71O)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
Product Characteristics			
Color	RED, GREEN	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L;8
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0588-7	1 in 1 CARTON	03/17/2008	11/20/2014
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-0588-8	1 in 1 CARTON	03/17/2008	
2		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11822-0588-4	1 in 1 CARTON	03/17/2008	
3		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL		part341	03/17/2008	

**Labeler** - Rite Aid Corporation (014578892)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-0588)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11822-0588)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(11822-0588)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(11822-0588)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(11822-0588)

Revised: 5/2020

Rite Aid Corporation