

**SINUS CONGESTION AND PAIN DAYTIME- acetaminophen and phenylephrine hcl tablet  
Wal-Mart Stores Inc**

*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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**Equate 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
  - nasal congestion
  - sinus congestion and pressure
  - minor aches and pains
- 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 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

**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**

- heart disease
- diabetes
- liver disease
- thyroid disease
- 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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.**

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 10 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**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

***Inactive ingredients***

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, pregelatinized starch, propylene glycol, shellac glaze, silica gel, stearic acid, titanium dioxide

**Questions or comments?**

**1-888-287-1915**

**Principal Display Panel**

NDC 49035-558-22

**equate™**

**Compare to  
Tylenol® SINUS  
+ HEADACHE  
Day Active  
Ingredients\***

**Rapid Release  
Sinus  
Congestion  
& Pain**

**Acetaminophen, Phenylephrine HCl**  
Pain Reliever, Fever Reducer, Nasal Decongestant

**Daytime Non-Drowsy**

- Sinus headache & pressure
- Nasal congestion

**48 GELCAPS**

Actual Size

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

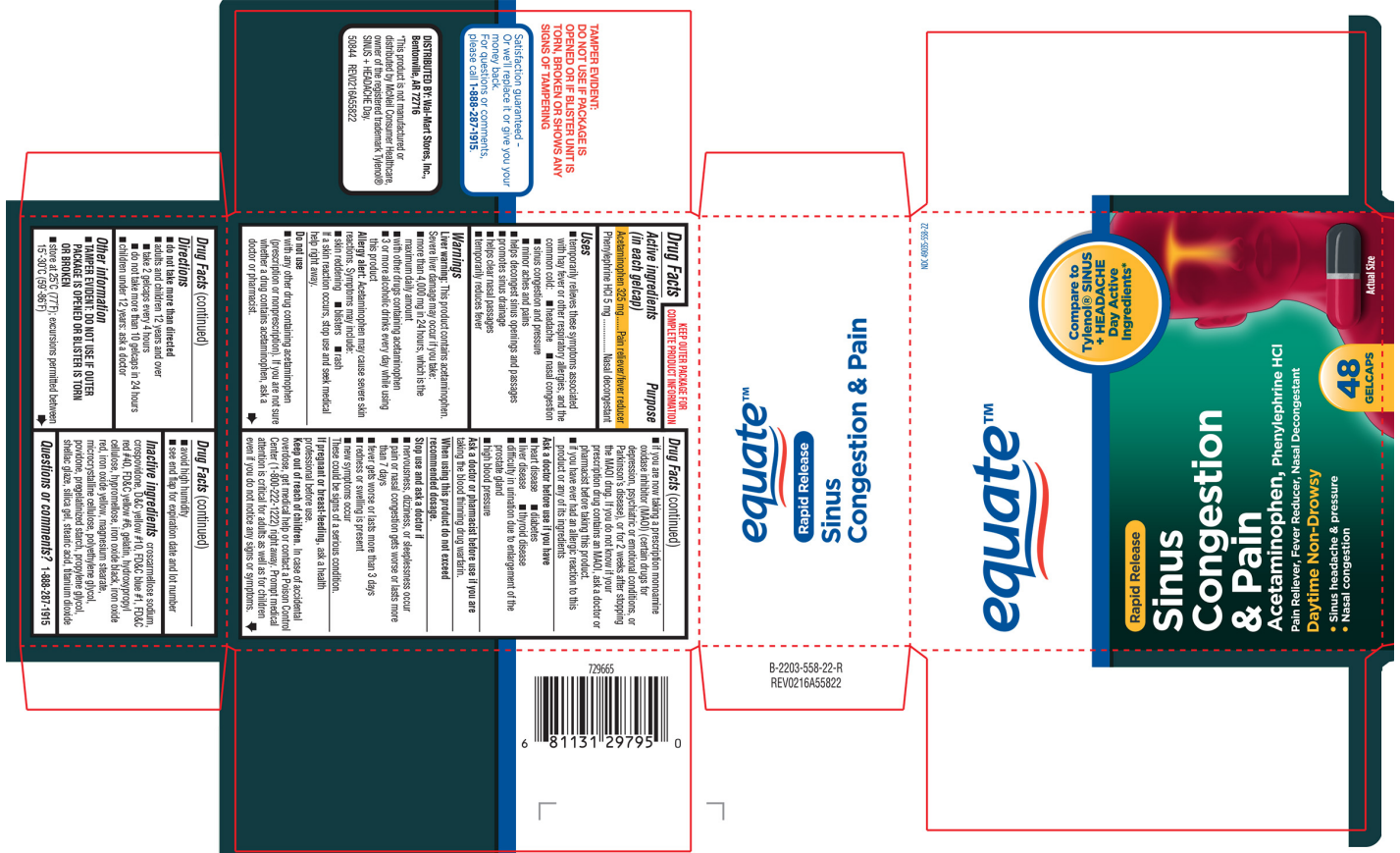
Satisfaction guaranteed -  
Or we'll replace it or give you your  
money back.

For questions or comments,  
please call **1-888-287-1915**.

**DISTRIBUTED BY: Wal-Mart, Inc.,  
Bentonville, AR 72716**

\*This product is not manufactured or  
distributed by McNeil Consumer Healthcare,  
owner of the registered trademark Tylenol®  
SINUS + HEADACHE Day.

50844 REV0216A55822



Equate 44-558

## SINUS CONGESTION AND PAIN DAYTIME

acetaminophen and phenylephrine hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-558
<b>Route of Administration</b>	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)	
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)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

### Product Characteristics

Color	RED (red, green and gray in the middle) , 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:49035-558-22	4 in 1 CARTON	03/17/2008	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49035-558-42	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	03/17/2008	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/17/2008	

**Labeler** - Wal-Mart Stores Inc (051957769)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(49035-558)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(49035-558)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(49035-558)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(49035-558)

Revised: 8/2017

Wal-Mart Stores Inc