# SINUS CONGESTION AND PAIN- acetaminophen and phenylephrine hydrochloride capsule 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 Nasal decongestant

#### Uses

- for the temporary relief of:
  - headache
  - sinus congestion and pressure
  - minor aches and pains
  - nasal congestion
- helps decongest sinus openings and passages
- promotes sinus drainage
- helps clear nasal passages

### Warnings

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

- more than 12 gelcaps 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

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

#### Ask a doctor or pharmacist before use if

taking the blood thinning drug warfarin

#### When using this product

do not exceed recommended dos age

#### 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 of 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.

**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. Quick 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 (see overdose warning)
- 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: 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 controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### **Inactive ingredients**

croscarmellose sodium, croscpovidone, 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?

Call toll free: 1-800-426-9391

#### **Principal Display Panel**

NDC 49035-558-22

SEE NEW WARNINGS INFORMATION

#### equate®

## Compare to Tylenol® Sinus Congestion & Pain Daytime Active Ingredients\*

Sinus

Congestion

& Pain

Pain Reliever, Nasal Decongestant

## **Daytime Non-Drowsy**

- Headache **Acetaminophen**
- Sinus pressure, nasal congestion Phenylephrine HCl

#### 48 GELCAPS

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Sinus Congestion & Pain Daytime.

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

#### Cuestions? (all to 1:ess-1:ess-1:ess-1915)

polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, silica gel, steanc acid, fitanium doxide cellulose, hypromeliose, fron avide black, fron avide red, fron avide yellow, magnesum stearste, microcrystaline cellulose, croscarmellose sodium, crospovidone, D&C yellow #10, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl

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Drug Facts (continued)

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Sinus Congestion & Pain Daytime.

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Distributed by: Wel-Mart Stores, Inc., Bentomille, AR 72716

bjesse cell 1-888-287-1915.

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DO NOT USE IF CARTON IS OPENED

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Sinus **Congestion & Pain** 

SEE NEW WARNINGS INFORMATION



Compare to Tylenol® Sinus Congestion **Pain Daytime** Active Ingredients'

Congestion

B-2203-558-22 REV1209855822

**Equate 44-558** 

## SINUS CONGESTION AND PAIN

acetaminophen and phenylephrine hcl capsule

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:49035-558
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	325 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM			
CROSPOVIDONE			
D&C YELLOW NO. 10			
FD&C BLUE NO. 1			
FD&C RED NO. 40			
HYDROXYPROPYL CELLULOSE (TYPE H)			
HYPROMELLOSES			
MAGNESIUM STEARATE			
POLYETHYLENE GLYCOLS			
STEARIC ACID			
TITANIUM DIO XIDE			

Product Characteristics			
Color	RED	Score	score with uneven pieces
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	44;558
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-558-22	1 in 1 CARTON		

1	18 in 1 BLISTER PACK		
• • - •			
Marketing Information			
Marketing Category	Application Number or Monograph Ci	itation Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINA	L part343	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.		832867894	MANUFACTURE(49035-558)	

Revised: 11/2012 Wal-Mart Stores Inc