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.

Equate 44-558-Delisted

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 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

- 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 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- avoid high humidity
- 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?

1-888-287-1915

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: Walmart Inc., Bentonville, AR 72716

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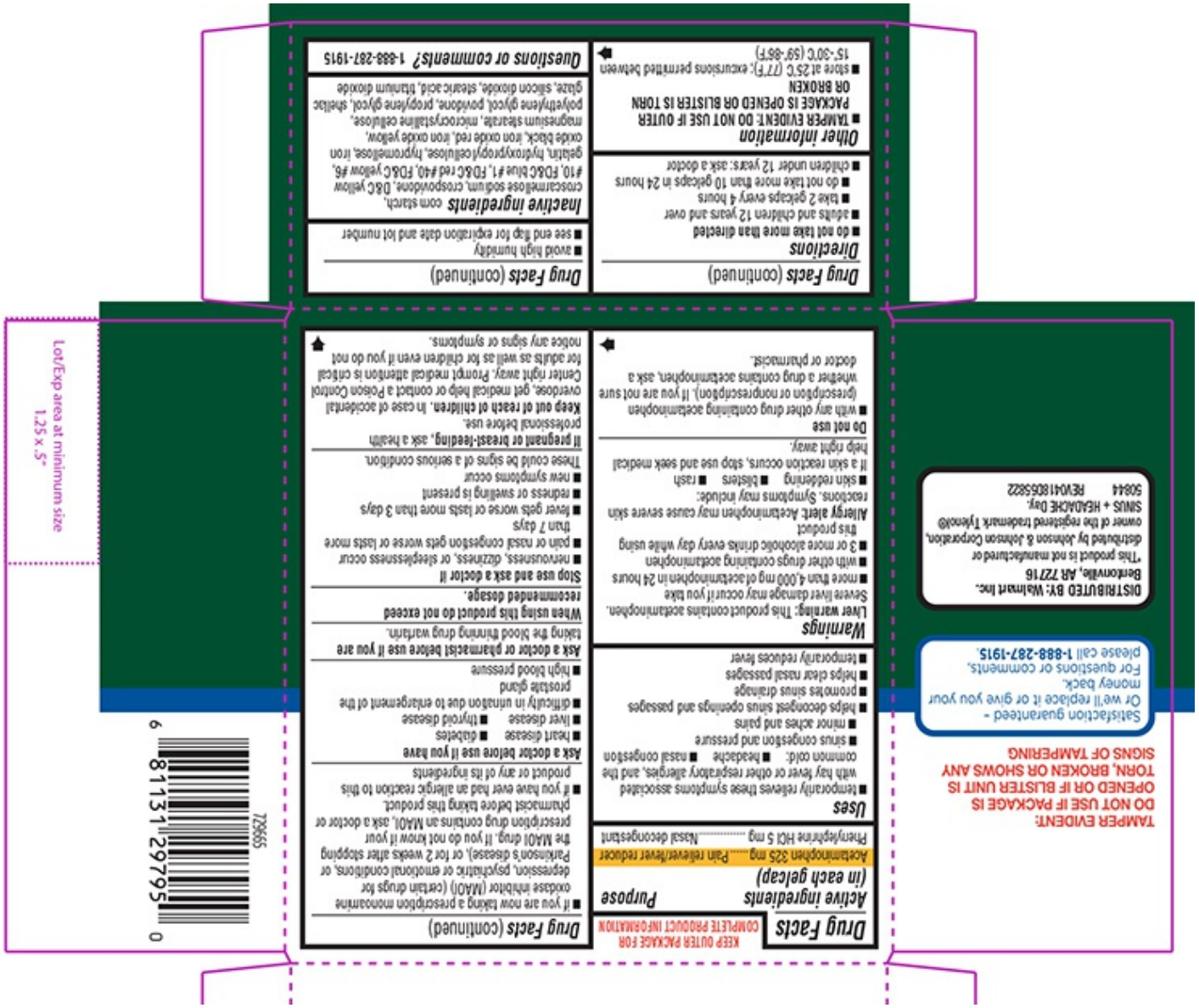

Equate 44-558

SINUS CONGESTION AND PAIN DAYTIME

acetaminophen and phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49035-558
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)	

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: 3WQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSOFERRIC 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)	
CROSPOVIDONE (UNII: 2S7830E561)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	

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	12/31/2025
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	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2008	12/31/2025

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.		832867894	manufacture(49035-558)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(49035-558)

Establishment

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

Revised: 9/2023 Wal-Mart Stores Inc