

SINUS AND HEADACHE- acetaminophen, phenylephrine hcl tablet, film coated
Meijer Distribution 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.

Meijer Distribution, Inc. Sinus + Headache Drug Facts

Active ingredients (in each caplet)

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 upper respiratory allergies, and the common cold:
- headache
- sinus congestion and pressure
- nasal congestion
- 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

- 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

- 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.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 caplets every 4 hours
- swallow whole – do not crush, chew or dissolve

	<ul style="list-style-type: none">do not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

Inactive ingredients

acesulfame potassium, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Tylenol® Sinus + Headache active ingredients

Non-Drowsy

Sinus + Headache

Acetaminophen

Phenylephrine HCl

Pain Reliever/Fever Reducer; Nasal Decongestant For Adults

Daytime

Sinus Headache

Sinus Pressure

Nasal Congestion

Actual Size

24 Caplets

NDC 41250-849-62

meijer

Compare to Tylenol® Sinus + Headache
active ingredients*

Non-Drowsy

Sinus + Headache

Acetaminophen • Phenylephrine HCl
Pain Reliever/Fever Reducer, Nasal Decongestant
For Adults

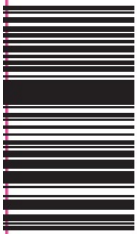
Daytime

Sinus Headache
Sinus Pressure
Nasal Congestion



Actual Size

24 Caplets





DIST. BY MEIJER DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com



Important: Read all product information before using. Keep this box for important information.

27262 6E C10

Drug Facts		Drug Facts (continued)	
Active ingredients (in each caplet)	Purpose	<ul style="list-style-type: none"> 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 	
Acetaminophen 325 mg.....	Pain reliever/fever reducer	Ask a doctor before use if you have <ul style="list-style-type: none"> liver disease heart disease high blood pressure thyroid disease diabetes trouble urinating due to an enlarged prostate gland 	
Phenylephrine HCl 5 mg.....	Nasal decongestant	Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin	
Uses		When using this product do not exceed recommended dosage	
<ul style="list-style-type: none"> temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: <ul style="list-style-type: none"> headache sinus congestion and pressure nasal congestion minor aches and pains helps decongest sinus openings and passages promotes sinus drainage helps clear nasal passages temporarily reduces fever 		Stop use and ask a doctor if <ul style="list-style-type: none"> 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.	
Warnings		If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> skin reddening blisters rash If a skin reaction occurs, stop use and seek medical help right away.			
Do not use			
<ul style="list-style-type: none"> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 			

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

Drug Facts (continued)
Questions or comments? 1-800-719-9260
Store at 20-25°C (68-77°F).
DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Drug Facts (continued)		Drug Facts (continued)	
Directions	do not take more than directed (see overdose warning)	Inactive ingredients acesulfame potassium, carnauba wax, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, flavor, lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide	
adults and children 12 years and over	<ul style="list-style-type: none"> take 2 caplets every 4 hours swallow whole – do not crush, chew or dissolve do not take more than 10 caplets in 24 hours 		
children under 12 years	ask a doctor		

SINUS AND HEADACHE

acetaminophen, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-849
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	GREEN	Score	no score
Shape	CAPSULE	Size	16mm
Flavor	VANILLA (menthol)	Imprint Code	L272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-849-62	12 in 1 CARTON	03/28/2017	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/28/2017	

Labeler - Meijer Distribution Inc (006959555)