

## **SMART SENSE SINUS AND HEADACHE- acetaminophen, phenylephrine hcl tablet, film coated**

**Kmart 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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### **Kmart Corporation 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)

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adults and children 12 years and over	<ul style="list-style-type: none"> <li>• take 2 caplets every 4 hours</li> <li>• swallow whole – do not crush, chew or</li> </ul>
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	dissolve
	<ul style="list-style-type: none"><li>do not take more than 10 caplets in 24 hours</li></ul>
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

### **Principal Display Panel**

COMPARE TO ACTIVE INGREDIENTS IN TYLENOL® SINUS + HEADACHE

ACTUAL SIZE

daytime

sinus + headache

ACETAMINOPHEN, PHENYLEPHRINE HCl

PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT FOR ADULTS

RELIEVES:

SINUS HEADACHE

NASAL CONGESTION

SINUS PRESSURE

24 CAPLETS

smart  
sense®



ACTUAL SIZE

NDC 49738-563-62

COMPARE TO  
ACTIVE INGREDIENTS  
IN TYLENOL®  
SINUS + HEADACHE®

daytime

# sinus + headache

ACETAMINOPHEN, PHENYLEPHRINE HCl  
PAIN RELIEVER / FEVER REDUCER, NASAL DECONGESTANT  
FOR ADULTS

**RELIEVES:**

SINUS HEADACHE • NASAL CONGESTION  
SINUS PRESSURE

24  
CAPLETS



\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Sinus + Headache.

**SATISFACTION GUARANTEE**

If you are unsatisfied for any reason, return the un used portion to the store for a full refund or call 1-800-842-7886.

gf  
GLUTEN  
FREE

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

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Acetaminophen 325 mg.....	Pain reliever/fever reducer
Phenylephrine HCl 5 mg.....	Nasal decongestant

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### Drug Facts (continued)

- 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.
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Distributed by:  
Kmart Corporation  
Hoffman Estates, IL 60179  
Shop kmart.com

Drug Facts (continued)  
Questions or comments? 1-800-719-0260  
Store at 20-25°C (68-77°F)  
DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

### Drug Facts (continued)

**Directions** ■ do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"> <li>take 2 caplets every 4 hours</li> <li>swallow whole – do not crush, chew or dissolve</li> <li>do not take more than 10 caplets in 24 hours</li> </ul>
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### Drug Facts (continued)

**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

27262 FT C6

COOLING ANALGESIC

# SMART SENSE SINUS AND HEADACHE

acetaminophen, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49738-563
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49738-563-62	12 in 1 CARTON	04/05/2017	
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	04/05/2017	

**Labeler** - Kmart Corporation (008965873)

Revised: 12/2019

Kmart Corporation