# GOOD SENSE SINUS PLUS HEADACHE- acetaminophen, phenylephrine hcl tablet, film coated L. Perrigo Company

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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#### Perrigo 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

	• do not take more than 10 caplets in 24 hours
children under 12	ask a doctor
years	

#### **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**

For Adults

Non-Drowsy

Daytime

Sinus + Headache

Pain Reliever-Fever Reducer/Acetaminophen

Nasal Decongestant/Phenylephrine HCl

Actual Size

Sinus Pressure Headache-Nasal Congestion

Sinus Pressure

Compare to active ingredients of Tylenol® Sinus + Headache

100% SATISFACTION GUARANTEED

24 Caplets

## GOODSENSE.

NDC 0113-0066-62

For Adults

# Non-Drowsy Daytime Sinus + Headache

Pain Reliever • Fever Reducer/Acetaminophen Nasal Decongestant/Phenylephrine HCl



- Sinus Headache
   Nasal Congestion
- Sinus Pressure

24 Caplets

Compare to active ingredients of Tylenol® Sinus + He adache



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

#### Drug Facts

Active ingredients (in each caplet)

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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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Ask a doctor before use if you have

- heart disease high blood pressure diabetes ■ liver disease
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Store at 20-25°C (68-77°F). Do not use if Blister unit is broken or topn Drug Facts (continued)
Questions or comments? 1-800-719-9260

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Drug Facts (continued)

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## GOOD SENSE SINUS PLUS HEADACHE

acetaminophen, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0066
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME PO TASSIUM (UNII: 23OV73Q5G9)	
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:0113-0066-62	12 in 1 CARTON	04/21/2017	
1	2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final part341 04/21/2017

# Labeler - L. Perrigo Company (006013346)

Revised: 12/2019 L. Perrigo Company