

SINUS HEADACHE PE- acetaminophen and phenylephrine hydrochloride tablet

Safeway

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.

Safeway 44-502

Active ingredients (in each caplet)

Acetaminophen 325 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Nasal decongestant

Uses

- temporarily relieves headache, minor aches and pains
- temporarily relieves nasal congestion

Warnings

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

- more than 12 caplets 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 an 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

- 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: 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 use more than directed (see overdose warning)**
- adults and children 12 years and over
- take 2 caplets every 4 hours
- do not take more than 12 caplets 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

corn starch, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone, silica gel, stearic acid

Principal Display Panel

NDC 21130-766-21

Compare to Sudafed PE® Sinus Headache active ingredients*

Maximum Strength

Sinus Headache PE

Acetaminophen 325 mg,

•Helps Prevent Nausea and Dizziness Due to Motion Sickness

32 TABLETS

SAFEWAY™

50844 REV1011D40327

DISTRIBUTED BY SAFEWAY INC., P.O. BOX 99, PLEASANTON, CA 94566-009

QUALITY & SATISFACTION GUARANTEED OR YOUR MONEY BACK

1-888-SAFEWAY / www.safeway.com

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

Maximum Strength Sinus Headache PE

Maximum Strength Sinus Headache PE

NDC 21130-766-21
Compare to Sudafed PE® Sinus Headache active ingredients*

Acetaminophen 325 mg,
Phenylephrine HCl 5 mg

- Sinus Pain & Headache
- Sinus Pressure
- Nasal & Sinus Congestion



ACTUAL SIZE

24 CAPLETS

SAFEMAY



RD 11339

OMIT B

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

*This product is not manufactured or distributed by Major Consumer Healthcare distributors of Sudafed PE® Sinus Headache.
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B-1817-502-08
REV0410E50208

<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> ■ store at controlled room temperature 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number 	<p>Drug Facts (continued)</p> <p>Inactive ingredients corn starch, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone, silica gel, stearic acid</p> <p>Questions or comments? 1-800-426-9391</p>
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<p>Drug Facts</p> <p>Active ingredients (in each caplet)</p> <p>Acetaminophen 325 mg Phenylephrine HCl 5 mg</p> <p>Purpose Pain reliever Nasal decongestant</p> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves headache, minor aches and pains ■ temporarily relieves nasal congestion <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> ■ more than 12 caplets 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 <p>Do not use</p> <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. ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or 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 <p>Directions ■ do not use more than directed (see overdose warning)</p> <ul style="list-style-type: none"> ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ do not take more than 12 caplets 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 <p>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.</p> <p>Keep out of reach of children.</p> <p>If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition:</p> <ul style="list-style-type: none"> ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days ■ pain or nasal congestion gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ when using this product ■ do not exceed recommended dosage ■ taking the blood thinning drug warfarin <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ taking the blood thinning drug warfarin ■ 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 <p>Drug Facts (continued)</p>	<p>Drug Facts (continued)</p> <p>Directions ■ do not use more than directed (see overdose warning)</p> <ul style="list-style-type: none"> ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ do not take more than 12 caplets 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 <p>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.</p> <p>Keep out of reach of children.</p> <p>If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition:</p> <ul style="list-style-type: none"> ■ redness or swelling is present ■ fever gets worse or lasts more than 3 days ■ pain or nasal congestion gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ when using this product ■ do not exceed recommended dosage ■ taking the blood thinning drug warfarin <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ taking the blood thinning drug warfarin ■ 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 <p>Drug Facts (continued)</p>
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C740

LEBG653X

SINUS HEADACHE PE

acetaminophen and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:21130-766
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
CROSPVIDONE	
FD&C YELLOW NO. 6	
MAGNESIUM STEARATE	
POVIDONES	
STEARIC ACID	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	44;502
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-766-08	1 in 1 CARTON		
1		24 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	06/23/2005	

Labeler - Safeway (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		038154464	PACK(21130-766)
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Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(21130-766)

Revised: 11/2012

Safeway