

SINUS HEADACHE PE MAXIMUM STRENGTH- acetaminophen and phenylephrine hcl tablet Better Living Brands, LLC

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_Delisted

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 25°C (77°F); excursions permitted between 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® Pressure + Pain active ingredients*

Maximum Strength

Sinus Headache PE

Acetaminophen 325 mg,

•Helps Prevent Nausea and Dizziness Due to Motion Sickness

24 TABLETS

SAFEWAY™

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE® Pressure + Pain. 50844 REV1012F40327

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



Safeway 44-502

SINUS HEADACHE PE MAXIMUM STRENGTH

acetaminophen and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-766
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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	2 in 1 CARTON		
1		12 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 NOT FINAL	part343	06/23/2005	06/23/2018

Labeler - Better Living Brands, LLC (009137209)

Establishment

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

Establishment

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

Revised: 7/2015

Better Living Brands, LLC