PAIN RELIEF NON DROWSY DAYTIME- acetaminophen, 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.

Signature Care 44-466C

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 respiratory allergies, and the common cold:
 - minor aches and pains
 - headache
 - nasal congestion
 - sinus congestion and pressure
- 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:

- blisters
- rash
- skin reddening

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
- difficulty in urination due to enlargement of the prostate gland
- heart disease
- diabetes
- thyroid disease
- high blood pressure

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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present

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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- 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 years: ask a doctor

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- 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, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C red

#40 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

SignatureTM

care

Quality

Guaranteed

COMPARE TO

 $Tylenol^{\circledR}$

SINUS + HEADACHE

active ingredients*

NDC 21130-466-08

Non-Drowsy Daytime

Pain Relief

Sinus Congestion

ACETAMINOPHEN 325 mg

- Pain Reliever / Fever Reducer PHENYLEPHRINE HCl 5 mg

- Nasal Decongestant

Relief of:

Headache, sinus pressure, nasal congestion

Actual Size

24 CAPLETS

*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributors of Tylenol® SINUS + HEADACHE.

50844 REV0818B46608

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

DISTRIBUTED BY BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 1-888-723-3929 www.betterlivingbrandsLLC.com

OUR PROMISE

QUALITY & SATISFACTION 100% GUARANTEED

OR YOUR MONEY BACK.

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Drug Facts (continued)

Nasal decongestant Phenylephrine HCI 5 mg Pain reliever/fever reducer cetaminophen 325 mg

> (in each caplet) Active ingredients

COMPLETE PRODUCT KEEP OUTER PACKAGE FOR

Purpose

Drug Hacts



COMPARE TO Tylenol® SINUS + HEADACHE active ingredients

NDC 21130-466-08

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Non-Drowsy Daytime Pain Relief Sinus Congestion

ACETAMINOPHEN 325 mg

- Pain Reliever/Fever Reducer PHENYLEPHRINE HCI 5 mg

Nasal Decongestant

Actual Size



Relief of: Headache, sinus pressure, nasal congestion

24 CAPLETS

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REV0818B46608

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OUR PROMISI

Scan here for more information

OR SHOWS ANY SIGNS OF TAMPERING

Questions or comments? 1-800-426-9391

sucralose, talc, titanium dioxide silicon dioxide, sodium starch glycolate, stearic acid,

(continued)

polyethylene glycol, polyvinyl alcohol, povidone, flavor, magnesium stearate, microcrystalline cellulose, blue #1 aluminum lake, FD&C red #40 aluminum lake, crospovidone, D&C yellow #10 aluminum lake, FD&C INACTIVE INGREDIEMIS corn starch,

B-1817-466C-08SCS REV0818B46608 <u>ത</u>

Drug Facts (continued)

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■ store at 25°C (77°F); excursions permitted between

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Signature Care 44-466C

PAIN RELIEF NON DROWSY DAYTIME

acetaminophen, phenylephrine hcl tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-466	
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: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPO VIDO NE (UNII: 2S7830 E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	17mm	
Flavor	MINT	Imprint Code	44;466	
Contains				

	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 ND	C:21130-466-08	2 in 1 CARTON	07/26/2005		
ı	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 FINAL	part341	07/26/2005			

Labeler - Better Living Brands, LLC (009137209)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(21130-466)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	PACK(21130-466)	

Revised: 5/2020 Better Living Brands, LLC