SINUS CONGESTION AND PAIN MAXIMUM STRENGTH- acetaminophen, phenylephrine hcl tablet
Rugby Laboratories

Rugby 44-502

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:
  - minor aches and pains
  - nasal congestion
  - headache
  - sinus congestion and pressure
- promotes sinus drainage
- 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

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

In case of accidental overdose, get medical help or contact a Poison Control Center 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 use more than directed**
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - 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, croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, stearic acid

Questions or comments?

1-800-645-2158

Principal display panel

Rugby®

NDC 0536-1289-35

Compare to the
active ingredients in
SUDAFED PE®
SINUS PRESSURE + PAIN*

Maximum Strength
Sinus Congestion and Pain
Acetaminophen 325 mg/Phenylephrine HCl 5 mg

325 mg/5 mg

Pain Reliever/Fever Reducer
and Nasal Decongestant

Relieves
Sinus Headache, Sinus Pressure, Nasal Congestion
Non-Drowsy

Actual size
24 Caplets

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

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark SUDAFED PE® SINUS PRESSURE + PAIN.
50844 REV0820A50208

Rev. 01/21 R-17 Reorder No. 371023

Distributed by:

RUGBY® LABORATORIES
Livonia, MI 48152
www.rugbylaboratories.com

Rugby 44-502

SINUS CONGESTION AND PAIN MAXIMUM STRENGTH

acetaminophen, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1289
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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	44;502
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1289-35	2 in 1 CARTON	05/21/2020	
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 Drug	M012	05/21/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0536-1289) , pack(0536-1289)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0536-1289)

Revised: 2/2025 Rugby Laboratories