SINUS PRESSURE AND PAIN AND COUGH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
Target Corporation

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.

Target 44-617

Active ingredients

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - sinus congestion and pressure
  - minor aches and pains
  - cough due to the common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily promotes nasal and/or sinus drainage

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

- heart disease
- diabetes
- thyroid disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- liver disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- 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, nasal congestion, or cough 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
- cough comes back or occurs with rash or headache that lasts. 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**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

Call 1-800-910-6874

Principal display panel

Compare to active ingredients in Maximum Strength
Mucinex® SINUS-MAX® Pressure, Pain & Cough*

NDC 11673-961-09

maximum strength
sinus pressure,
pain + cough

acetaminophen (pain reliever)
dextromethorphan HBr (cough suppressant)
guaifenesin (expectorant)
phenylephrine HCl (nasal decongestant)

relieves headache, sinus pressure and congestion
controls cough
thins and loosens mucus

20 CAPLETS

ACTUAL SIZE

Up & Up™

Distributed by Target Corporation
Minneapolis, MN 55403
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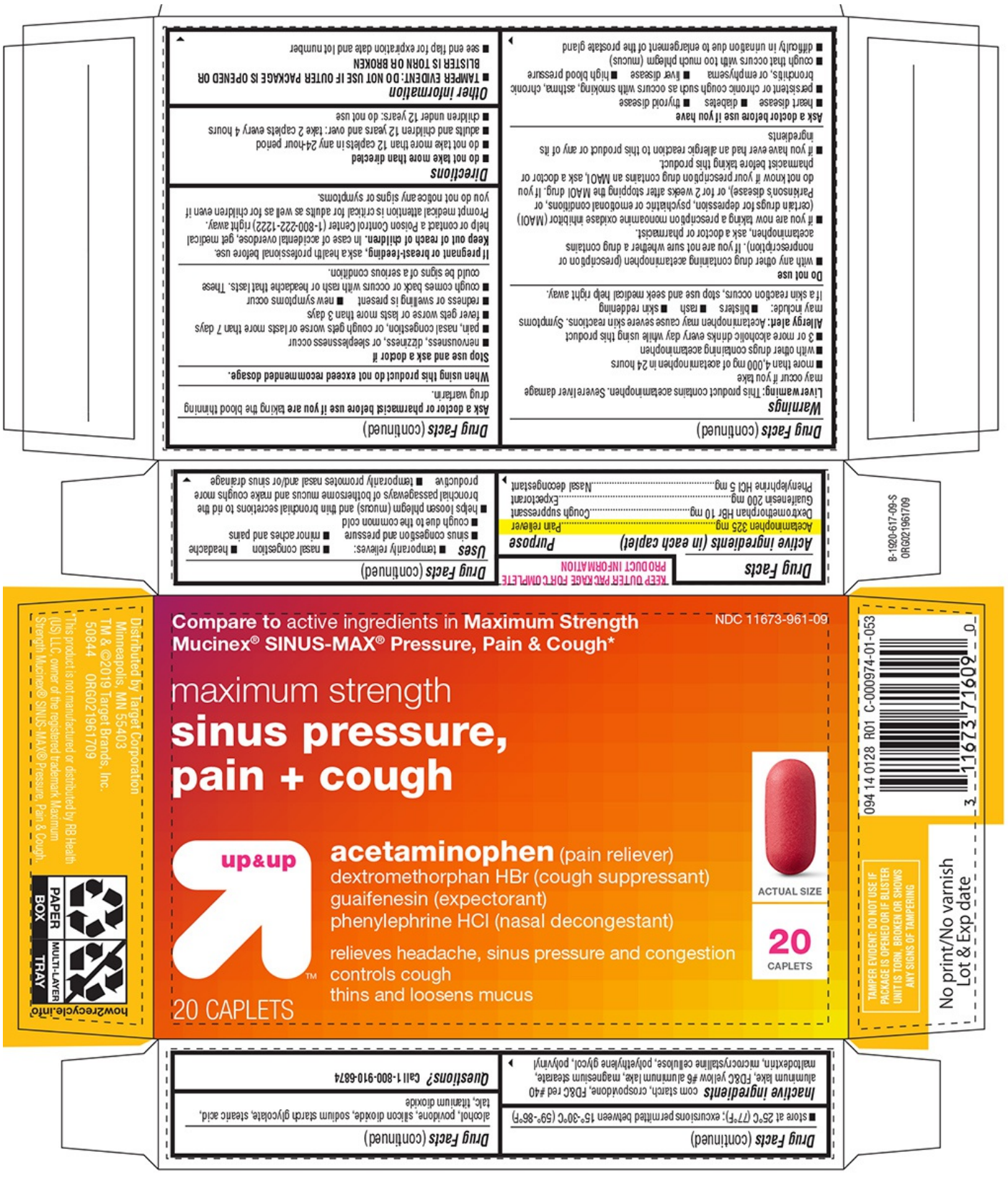
50844 ORG021961709

*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex® SINUS-MAX® Pressure, Pain & Cough.

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



Target 44-617

SINUS PRESSURE AND PAIN AND COUGH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-961
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE (UNII: FZ989GH94E)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CROSPOVIDONE (UNII: 2S7830E561)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;617
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-961-09	2 in 1 CARTON	08/30/2019	
1		10 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	08/30/2019	

Labeler - Target Corporation (006961700)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11673-961)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(11673-961)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11673-961)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(11673-961)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(11673-961)

Revised: 4/2020 Target Corporation