NASAL DECONGESTANT PE MAXIMUM STRENGTH- phenylephrine hcl tablet, film coated
Cardinal Health 110, LLC. DBA Leader

Leader 44-453

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

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.

Ask a doctor before use if you have

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

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets 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 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

LEADER™

NDC 70000-0126-2

Maximum Strength | Non-Drowsy

Nasal
Decongestant PE
Phenylephrine HCl, 10 mg | Nasal Decongestant

Sinus Pressure + Congestion
Pseudoephedrine-Free

18 TABLETS

Actual size

COMPARE TO SUDAFED
PE® SINUS CONGESTION
active ingredient*

100% Money Back Guarantee

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 Congestion.
50844 REV0820A45323

CardinalHealth™

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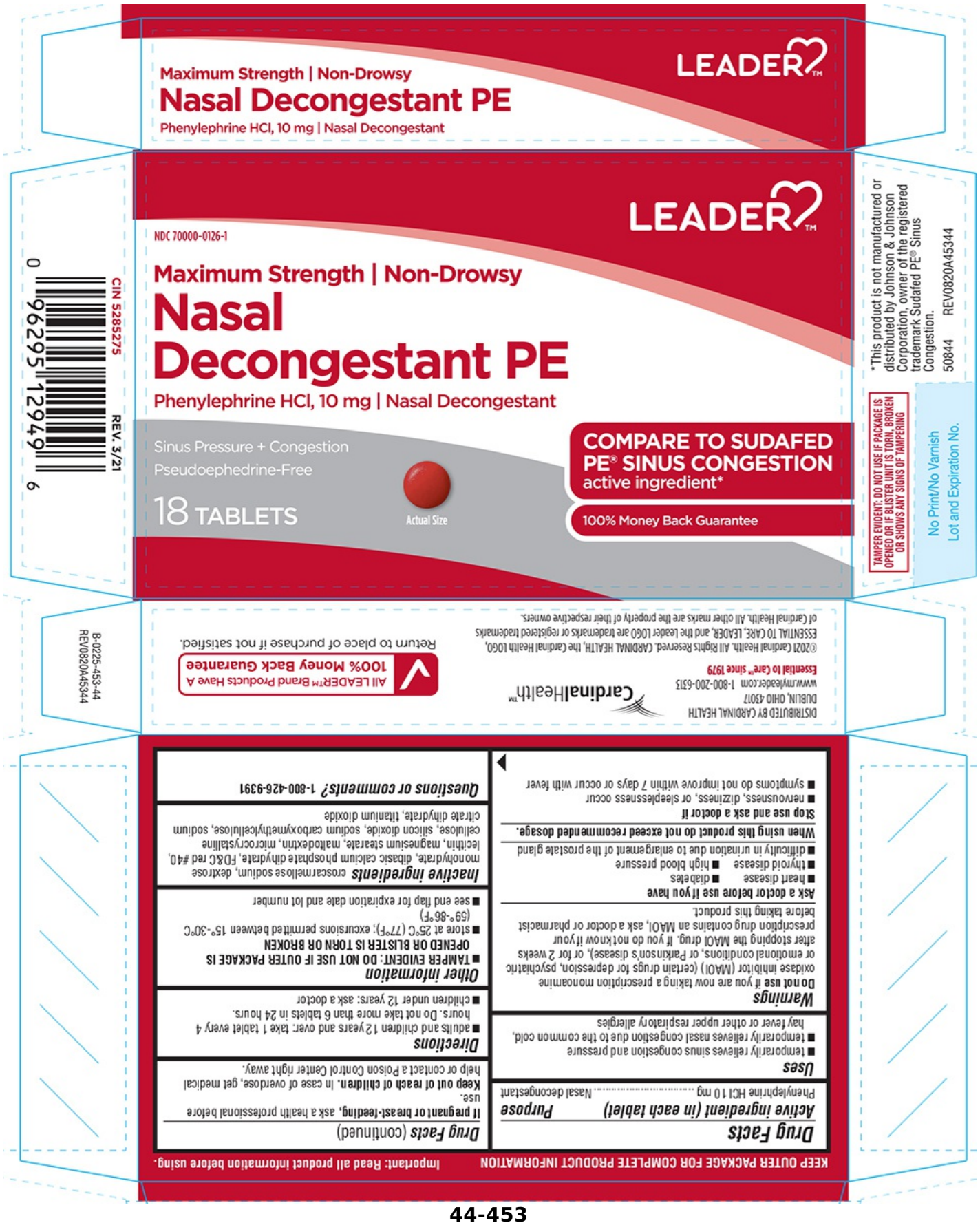
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

All LEADER™ Brand Products Have A
100% Money Back Guarantee
Return to place of purchase if not satisfied.



44-453

NASAL DECONGESTANT PE MAXIMUM STRENGTH

phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0126
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	44;453
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0126-1	1 in 1 CARTON	01/14/2005	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0126-2	3 in 1 CARTON	01/14/2005	
2		24 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	01/14/2005	

Labeler - Cardinal Health 110, LLC. DBA Leader (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0126) , pack(70000-0126)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0126)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70000-0126)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0126)

Revised: 4/2024 Cardinal Health 110, LLC. DBA Leader