

SUDOGEST- pseudoephedrine hcl tablet, film coated
Major Pharmaceuticals

Major 44-112

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 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

- heart disease
- diabetes
- thyroid disease
- high blood pressure
- 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 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	take 1 tablet every 4 to 6 hours; do not take more than 4 tablets in 24 hours
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 15 mg
- 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

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal Display Panel

NDC 0904-5053-59

Compare to the active ingredient in Sudafed® Sinus Congestion*

MAJOR®

Maximum Strength

SudoGest

Pseudoephedrine HCl

30 mg

NASAL DECONGESTANT

Relieves:

Sinus Pressure, Sinus Congestion

Actual Size

100 Tablets

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

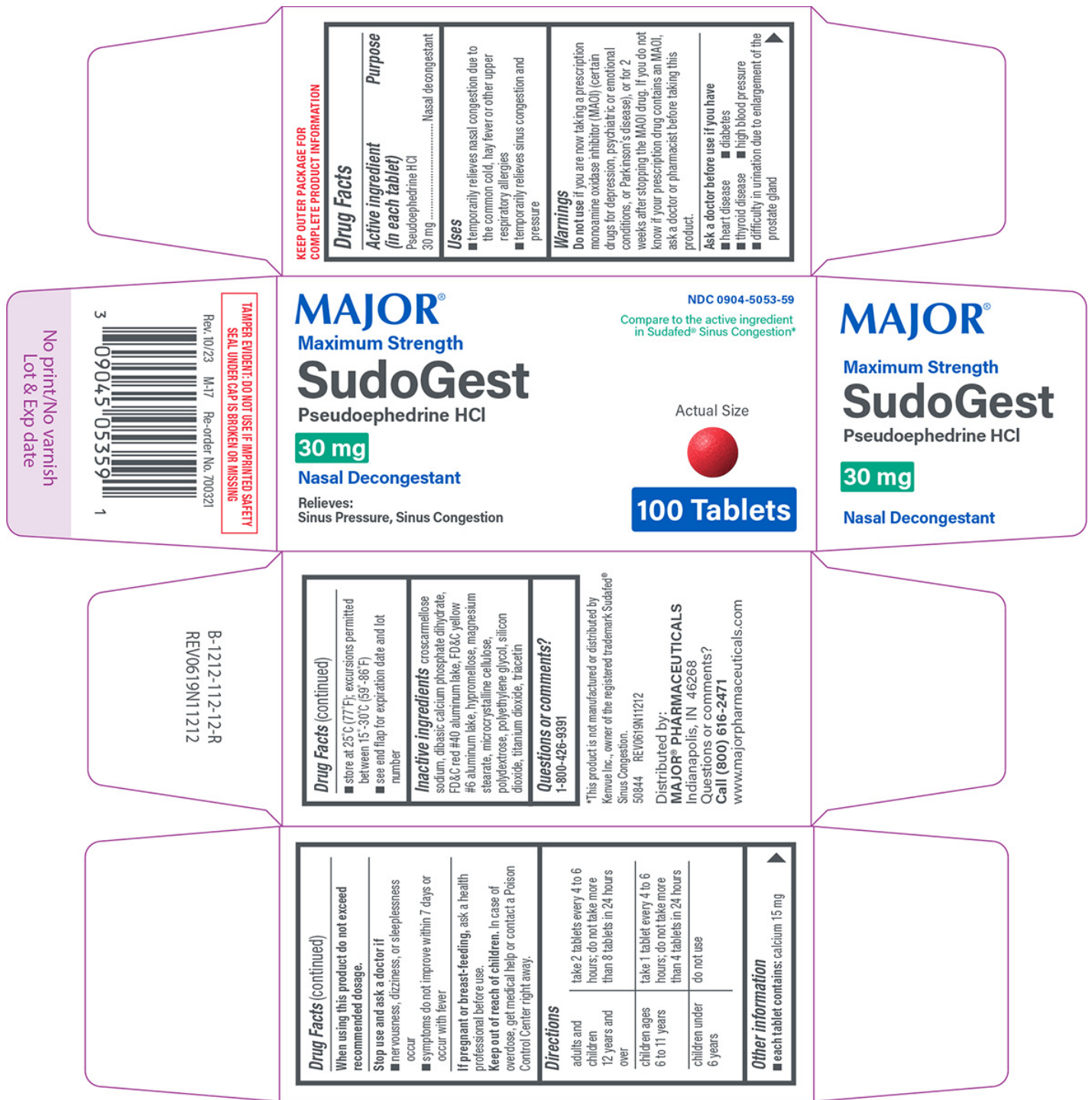
Questions or comments?

Call (800) 616-2471

www.majorpharmaceuticals.com

This product is not manufactured or distributed by
Kenvue Inc., owner of the registered trademark Sudafed®
Sinus Congestion.

50844 REV0619N11212



MAJOR 44-112

SUDOGEST

pseudoephedrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5053
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	44;112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5053-59	1 in 1 CARTON	08/25/1981	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0904-5053-24	1 in 1 CARTON	08/25/1981	11/11/2021
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	08/25/1981	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0904-5053)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-5053) , pack(0904-5053)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0904-5053)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0904-5053)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0904-5053)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-5053)

Revised: 12/2023

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