

SUDOGEST- chlorpheniramine maleate, pseudoephedrine hcl tablet

Major Pharmaceuticals

Major 44-111

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg
Pseudoephedrine HCl 60 mg

Purpose

Antihistamine
Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
 - runny nose
 - itchy, watery eyes
 - nasal congestion
 - sneezing
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing
 - 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

- a breathing problem such as emphysema or chronic bronchitis
- heart disease
- high blood pressure
- diabetes
- glaucoma
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- **do not exceed recommended dosage**
- drowsiness may occur
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a 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 to 6 hours. Do not take more than 4 tablets in 24 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**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- store in a dry place and protect from light
- see end flap for expiration date and lot number

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, lactose anhydrous, magnesium stearate, microcrystalline cellulose, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

MAJOR®

NDC 0904-5351-24

**Maximum Strength
SudoGest Sinus & Allergy**

**Chlorpheniramine Maleate 4 mg
Pseudoephedrine HCl 60 mg**

4 mg/60 mg

Antihistamine/Nasal Decongestant

**Runny Nose & Sneezing,
Itchy, Watery Eyes,
Sinus Congestion & Pressure**

24 Tablets

Actual Size

50844 REV0619L11108

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

Questions or comments?

Call (800) 616-2471

www.majorpharmaceuticals.com

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

Drug Facts (continued)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, lactose anhydrous, magnesium stearate, microcrystalline cellulose, stearic acid

Questions or comments? 1-800-426-9391

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

NDC 0904-5351-24

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Lot no. & Expiration Date

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Rev. 12/23 M-17 Re-order No. 235631



B-1212-111-08-R
REV0619L11108

Drug Facts

**KEEP OUTER PACKAGE FOR COMPLETE
PRODUCT INFORMATION**

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg Antihistamine
Pseudoephedrine HCl 60 mg Nasal decongestant

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SUDOGEST

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Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:0904-5351	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)			CHLORPHENIRAMINE MALEATE	4 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)			PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
Inactive Ingredients				
Ingredient Name				Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	white	Score	2 pieces	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	44;111	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5351-24	1 in 1 CARTON	12/16/1992	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-5351-96	2 in 1 CARTON	12/16/1992	01/31/2023
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	12/16/1992	

Labeler - Major Pharmaceuticals (191427277)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0904-5351) , pack(0904-5351)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0904-5351)

Revised: 2/2024

Major Pharmaceuticals