

SUDOGEST- chlorpheniramine maleate, pseudoephedrine hcl tablet

Major Pharmaceuticals

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.

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 dose**
- 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 (1-800-222-1222) 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?

(800) 616-2471

Principal Display Panel

MAJOR®

NDC 0904-5351-24

Maximum Strength

SudoGest Sinus & Allergy

Chlorpheniramine maleate 4 mg

Pseudoephedrine hydrochloride 60 mg

4 mg/ 60 mg

Antihistamine/Nasal Decongestant

Runny Nose & Sneezing,

Itchy, Watery Eyes,

Sinus Congestion & Pressure

24 Tablets

50844 REV0619K11108

Distributed by

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Rev. 10/19 M-17

Re-order No. 235631

**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

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MAJOR
Maximum Strength
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Chlorpheniramine maleate 4 mg
Pseudoephedrine HCl 60 mg

4 mg/60 mg

Antihistamine/Nasal Decongestant

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

Actual Size



24 Tablets

No Print Area
Lot no. & Expiration Date

B-1212-111-08-R
REV0619K11108

50844 REV0619K11108
Distributed by:
MAJOR PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
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Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredients (in each tablet)

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Pseudoephedrine HCl 60 mg Nasal decongestant

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Major 44-111

SUDOGEST

chlorpheniramine maleate, pseudoephedrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5351
Route of Administration	ORAL		

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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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 BOX	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	
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 FINAL	part341	12/16/1992	

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

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		832867894	MANUFACTURE(0904-5351)
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Establishment

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

Revised: 12/2019

Major Pharmaceuticals