SINUS AND ALLERGY- chlorpheniramine maleate and phenylephrine hydrochloride tablet Mckesson (Sunmark)

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.

DRUG FACTS

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg

Phenylephrine HCl 10 mg

Purpose

Antihistamine

Nasal decongestant

Uses

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

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

- high blood pressure
- heart disease
- glaucoma
- diabetes
- trouble urinating due to an enlarged prostate gland
- thyroid disease
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- drowsiness may occur
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or are accompanied by 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: 1-800-222-1222

Directions

- take every 4 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and older	take 1 tablet
children 6 to under 12 years of age	take 1/2 tablet
children under 6 years of age	consult a doctor
children under 4 years of age	**do not use**

Other information

- each tablet contains: Calcium 10 mg/ tablet
- store at 15º - 30º C (59º- 86º F)

Inactive ingredients

colloidal silicon dioxide, dicalcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, pregelatinized corn starch, sodium starch glycolate and stearic acid.

Questions or comments?

Call toll free 1-877-753-3935

Principal Display Panel

Compare to maximum strength sudafed PE® sinus &allergy active ingredients*

*This product is not manufactured or distributed by McNeil consumer healthcare, Division of McNeil-PPC, Inc. owner of the registered trademark Sudafed PE® Sinus and allergy

Maximum Strength Sinus & Allergy

For relief of: sinus pressure, sinus & nasal congestion, sneezing, itchy, watery eyes.

Chlorpheniramine Maleate 4 mg

Phenylephrine HCl 10 mg

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

TAMPER EVIDENT- USE ONLY IF BLISTERS ARE INTACT

Product Label

Sinus and allergy tablets

SINUS AND ALLERGY

chlorpheniramine maleate, phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49348-985
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	T127
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-985-04	1 in 1 CARTON		
1		24 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/07/2011	

Labeler - Mckesson (Sunmark) (177667227)

Revised: 9/2012 Mckesson (Sunmark)