PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release
HEB

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Pseudoephedrine HCl USP, 120 mg

PURPOSE

Nasal decongestant

USES

Temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

When using this product
- **do not use more than directed**

Stop use and ask a doctor if
- symptoms do not get better within 7 days or occur with a fever
- you get nervous, dizzy, or sleepless

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 older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

OTHER INFORMATION

- store at 59° to 77° F in a dry place
- protect from light
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

INACTIVE INGREDIENTS

Castor oil, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, magnesium stearate, titanium dioxide

QUESTIONS?

Call **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

Compare to Sudafed® 12 Hour active ingredient**

NDC 37808-0204-21

H.E.B®

12 HOUR DECONGESTANT

Long-Acting Nasal Decongestant

Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 120 mg

Non-Drowsy

- **Nasal & Sinus Congestion due to Colds & Allergies**
- **Sinus Pressure**
- **Maximum Strength**

20 Coated Caplets*120 mg EACH

(*Capsule-Shaped Tablets)

DISTRIBUTED BY H-E-B

5094507/0512

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-204
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	204
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-204-69	10 in 1 BLISTER PACK		
2	NDC:37808-204-21	20 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077442	04/28/2006	

Labeler - HEB (007924756)

Registrant - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(37808-204)