**SUDOGEST- pseudoephedrine hydrochloride tablet, film coated**
**Rebel Distributors Corp**

*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.*

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**SudoGest**
**Nasal Decongestant**

**Active ingredient**

Pseudoephedrine HCl 60 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**

- diabetes
- thyroid disease
- heart disease
- high blood pressure
- trouble urinating due to enlargement of the prostate gland

**When using this product**

- **do not exceed recommended dose**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

**If pregrant 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: take 1 tablet every 4 to 6 hours. Do not take more than 4 tablets in 24 hours.
- children under 12 years of age: do not use

**Other information**

- store at controlled room temperature 15˚-30˚C (59˚-86˚F)
- see end flap for expiration date and lot number

**Inactive ingredients**

corn starch, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, stearic acid

**Principal display panel**

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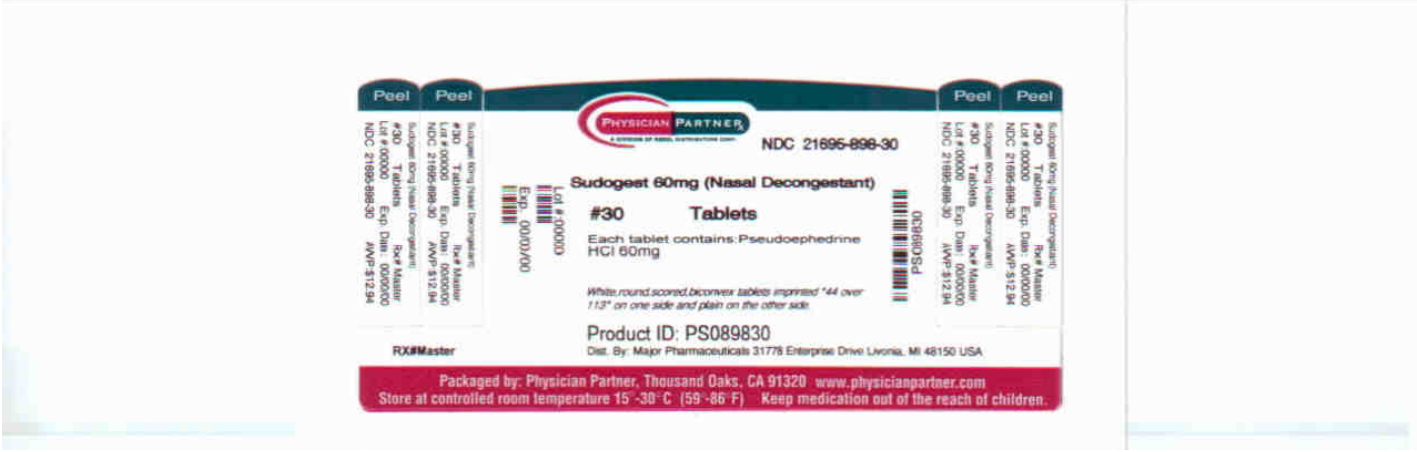


## SUDOGEST

pseudoephedrine hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:21695-898(NDC:0904-5125) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PSEUDOEPHEDRINE HYDROCHLORIDE** (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 60 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **LACTOSE** (UNII: J2B2A4N98G) | |

| | |
|---|---|
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **POLYETHYLENE GLYCOL** (UNII: 3WJQ0SDW1A) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | 44;113 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:21695-898-30 | 30 in 1 BOTTLE, PLASTIC | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 10/01/1994 | |

## Labeler - Rebel Distributors Corp (118802834)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rebel Distributors Corp | | 118802834 | RELABEL, REPACK |

Revised: 4/2011 Rebel Distributors Corp