

SUDAFED 12 HOUR- pseudoephedrine hydrochloride tablet, film coated, extended release
A-S Medication Solutions

SUDAFED 12 HOUR

Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product do not exceed recommended dosage

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. (1-800-222-1222)

Directions

| | |
|---------------------------------------|--|
| adults and children 12 years and over | <ul style="list-style-type: none">▪ take 1 tablet every 12 hours▪ do not take more than 2 tablets in 24 hours |
|---------------------------------------|--|

children under 12 years | do not use this product in children
under 12 years of age

Other information

- **each tablet contains:** calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- **do not use if blister unit is torn or broken**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP *Drug Release Test 3*

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

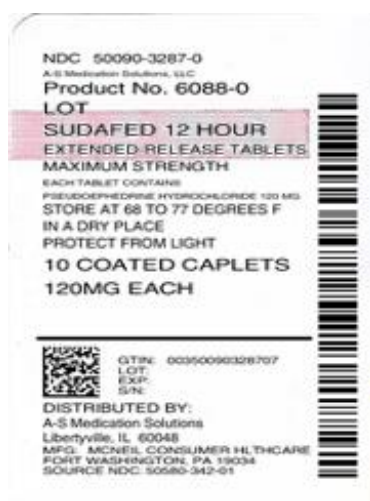
call 1-888-217-2117 (toll-free) or 215-273-8755 (collect)

HOW SUPPLIED

Product: 50090-3287

NDC: 50090-3287-0 10 TABLET, FILM COATED, EXTENDED RELEASE in a BLISTER PACK / 1 in a CARTON

Pseudoephedrine Hydrochloride



SUDAFED 12 HOUR

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

| | | | |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-3287(NDC:50580-342) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------|
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 120 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| carnauba wax (UNII: R12CBM0EIZ) | |
| silicon dioxide (UNII: ETJ7Z6XBU4) | |
| dibasic calcium phosphate dihydrate (UNII: O7TSZ97GEP) | |
| hypromellose, unspecified (UNII: 3NXW29V3WO) | |
| magnesium stearate (UNII: 70097M6I30) | |
| microcrystalline cellulose (UNII: OP1R32D61U) | |
| polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A) | |
| polysorbate 80 (UNII: 6OZP39ZG8H) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | SU12 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50090-3287-0 | 1 in 1 CARTON | 11/30/2017 | |
| 1 | | 10 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA075153 | 09/01/2017 | |

Labeler - A-S Medication Solutions (830016429)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-3287) |