

EPHEDRINE SULFATE- ephedrine sulfate tablet, film coated
Walgreen Company

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.

5789 - Walgreen

Drug Facts

Active ingredient (in each caplet)

Ephedrine Sulfate 25 mg

Purpose

Bronchodilator

Use

- for temporary relief of mild symptoms of intermittent asthma:
- wheezing tightness of chest shortness of breath

Asthma alert: Because asthma may be life threatening, see a doctor if you

- are not better in 60 minutes

- get worse

- need more than 6 caplets in 24 hours

- use more than 4 caplets in 24 hours for 3 or more days a week

- have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse.

- This product will not give you asthma relief as quickly as an inhaled bronchodilator.

Do not use

- unless a doctor said you have asthma

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs taken 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.

- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- ever been hospitalized for asthma

- heart disease

- high blood pressure

- diabetes

- thyroid disease
- seizures
- narrow angle glaucoma
- a psychiatric or emotional condition
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
- taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

When using this product

your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.

your risk of heart attack or stroke increases if you:

have a history of high blood pressure or heart disease

take this product more frequently or take more than the recommended dose

avoid foods or beverages that contain caffeine

avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect

Stop use and ask a doctor if

your asthma is getting worse (see Asthma alert)

you have difficulty sleeping

you have a rapid heart beat

you have tremors, nervousness, or seizure

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

do not take more than directed

| | |
|--|--|
| adults and children 12 years of age and over | take 1 caplet every 4 hours as needed. Do not take more than 6 caplets in 24 hours or as directed by a doctor. |
| children under 12 years of age | do not use |

Other information

- **each caplet contains:** calcium 20 mg
- store in a dry place at 15° - 30°C (59° - 86°F)

dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, polydextrose, silicon dioxide, sodium starch glycolate type A, talc, titanium dioxide.

Questions or comments?

Call 1-800-925-4733

RETAIN OUTER CARTON FOR COMPLETE PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF CARTON HAS BEEN OPENED OR BLISTER UNITS ARE TORN OR BROKEN

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

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PRODUCT OF INDIA MANUFACTURED AND PACKAGED IN THE U.S.A. USING DOMESTIC AND IMPORTED INGREDIENTS

††This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC., owner of the registered trademark Bronkaid®.

NDC 0363-5789-07

Walgreens

Compare to the active ingredient in Bronkaid® Max††

Asthma Relief

Ephedrine Sulfate 25 mg/ Bronchodilator

- Restores free breathing • Relief of mild intermittent asthma symptoms

60 Caplets



EPHEDRINE SULFATE

ephedrine sulfate tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-5789 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| EPHEDRINE SULFATE (UNII: U6X61U5ZEG) (EPHEDRINE - UNII:GN83C131XS) | EPHEDRINE SULFATE | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| TALC (UNII: 7SEV7J4R1U) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 15mm |
| Flavor | | Imprint Code | 57;89 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0363-5789-07 | 5 in 1 CARTON | 07/22/2022 | |
| 1 | | 12 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 | 07/22/2022 | |

Labeler - Walgreen Company (008965063)**Registrant** - Contract Pharmacal Corp. (057795122)

Revised: 9/2022

Walgreen Company