

EPHEDRINE SULFATE- ephedrine sulfate injection
Akorn, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

EPHEDRINE SULFATE
INJECTION USP, 50 mg/mL

For IM, IV or SC Use

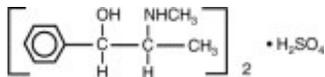
Rx only

DESCRIPTION

Ephedrine Sulfate Injection, USP is a sterile solution of 50 mg ephedrine sulfate in Water for Injection.

Ephedrine occurs as fine, white, odorless crystals or powder and darkens on exposure to light. It is freely soluble in water and sparingly soluble in alcohol.

The chemical name of ephedrine sulfate is $(C_{10}H_{15}NO)_2 \cdot H_2SO_4$ benzenemethanol α -[1 - (methylamino) ethyl] - sulfate (2:1) (salt). Its molecular weight is 428.54. The structural formula is:



CLINICAL PHARMACOLOGY

Ephedrine sulfate is a potent sympathomimetic that stimulates both α and β receptors and has clinical uses related to both actions. Its peripheral actions, which it owes in part to the release of norepinephrine, simulate responses that are obtained when adrenergic nerves are stimulated. These include an increase in blood pressure, stimulation of heart muscle, constriction of arterioles, relaxation of the smooth muscle of the bronchi and gastrointestinal tract, and dilation of the pupils. In the bladder, relaxation of the detrusor muscle is not prominent, but the tone of the trigone and vesicle sphincter is increased.

Ephedrine sulfate also has a potent effect on the CNS. It stimulates the cerebral cortex and subcortical centers, which accounts for its use in narcolepsy.

The cardiovascular responses reported in man include moderate tachycardia, unchanged or augmented stroke volume, enhanced cardiac output, variable alterations in peripheral resistance and usually a rise in blood pressure. The action of ephedrine is more prominent on the heart than on the blood vessels. Ephedrine sulfate increases the flow of coronary, cerebral and muscle blood.

In patients with myasthenia gravis, administration of Ephedrine Sulfate Injection, USP produces a real but modest increase in motor power. The exact mechanism by which ephedrine sulfate affects skeletal muscle contractions is unknown.

INDICATIONS AND USAGE

Ephedrine Sulfate Injection, USP is indicated in the treatment of allergic disorders, such as bronchial asthma. The drug has long been used as a pressor agent, particularly during spinal anesthesia when hypotension frequently occurs. In Stokes-Adams syndrome with complete heart block, ephedrine has a value similar to that of epinephrine. It is indicated as a central nervous system stimulant in narcolepsy and depressive states. It is also used in myasthenia gravis.

CONTRAINDICATIONS

Allergic reactions to ephedrine sulfate are rare. The hypersensitivity, if known, is a specific contraindication. Patients hypersensitive to other sympathomimetics may also be hypersensitive to ephedrine sulfate.

PRECAUTIONS

GENERAL - Special care should be used when administering Ephedrine Sulfate Injection, USP to patients with heart disease, angina pectoris, diabetes, hyperthyroidism, prostatic hypertrophy or hypertension and to patients receiving digitalis. Prolonged use may produce a syndrome resembling an anxiety state. Tolerance to ephedrine sulfate may develop, but temporary discontinuance to the drug restores its original effectiveness.

DRUG INTERACTIONS - Concurrent use of ephedrine sulfate with general anesthetics, especially cyclopropane or halogenated hydrocarbons or digitalis glycosides may cause cardiac arrhythmias, since these medications may sensitize the myocardium to the effects of ephedrine sulfate.

Therapeutic doses of ephedrine sulfate can inhibit the hypotensive effect of guanethidine, bethanidine, and debrisoquin by displacing the adrenergic blockers from their site of action in the sympathetic neurons. The effect in man is seen as a relative or a complete blockade of the antihypertensive drug by a sudden rise in blood pressure. Concomitant use of Ephedrine Sulfate Injection, USP and oxytocics may cause severe hypotension.

Monoamine oxidase inhibitors may potentiate the pressor effect of ephedrine sulfate, possibly resulting in a hypertensive crisis. Ephedrine Sulfate Injection, USP should not be administered during or within 14 days following the administration of MAO inhibitors.

PREGNANCY CATEGORY C - Animal reproduction studies have not been conducted with Ephedrine Sulfate Injection, USP. Also, it is not known whether the drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ephedrine Sulfate Injection, USP should be given to a pregnant woman only if clearly indicated.

It is not known what effect Ephedrine Sulfate Injection, USP may have on the newborn or on the child's later growth and development when the drug is administered to the mother just before or during labor.

NURSING MOTHERS - Ephedrine sulfate is excreted in breast milk. Use by nursing mothers is not recommended because of the higher than usual risks for infants.

ADVERSE REACTIONS

With large doses of ephedrine sulfate most patients will experience nervousness, insomnia, vertigo, headache, tachycardia, palpitation and sweating. Some patients have nausea, vomiting and anorexia. Vesical sphincter spasm may occur and result in difficult and painful urination. Urinary retention may develop in males with prostatism.

Precordial pain and cardiac arrhythmias may occur following administration of Ephedrine Sulfate Injection, USP

DRUG ABUSE AND DEPENDENCE

Prolonged abuse of Ephedrine Sulfate Injection, USP can lead to symptoms of paranoid schizophrenia. When this occurs, patients exhibit such physical signs as tachycardia, poor nutrition and hygiene, fever, cold sweat and dilated pupils.

Some measure of tolerance may develop with prolonged or excessive use but addiction does not occur. Temporary cessation of medication and subsequent readministration restores its effectiveness.

OVERDOSAGE

SYMPTOMS - The principal manifestation of ephedrine sulfate poisoning is convulsions. In acute poisoning the following signs and symptoms may occur: nausea, vomiting, chills, cyanosis, irritability, nervousness, fever, suicidal behavior, tachycardia, dilated pupils, blurred vision, opisthotonos, spasms, convulsions, pulmonary edema, gasping respirations, coma and respiratory failure. Initially, the patient may have hypertension, followed later by hypotension accompanied by anuria.

TREATMENT - If respirations are shallow or cyanosis is present, artificial respiration should be administered. Vasopressors are contraindicated. In cardiovascular collapse blood pressure should be maintained.

ANTIDOTE - For hypertension, 5 mg phentolamine mesylate diluted in saline may be administered slowly intravenously, or 100 mg may be given orally. Convulsions may be controlled by diazepam or paraldehyde. Cool applications and dexamethasone 1 mg/kg, administered slowly intravenously, may control pyrexia.

DOSAGE AND ADMINISTRATION

ADULTS - The usual parenteral dose is 25 to 50 mg given subcutaneously or intramuscularly. Intravenously, 5 to 25 mg may be administered slowly, repeated in 5 to 10 minutes, if necessary.

CHILDREN - The usual subcutaneous or intramuscular dose is 0.5 mg/kg of body weight or 16.7 mg/square meter of body surface every 4 to 6 hours.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Ephedrine Sulfate Injection USP, 50 mg/mL

1 mL ampules in packs of 10, NDC 17478-515-00

STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.

Akorn

Manufactured by: Akorn, Inc.

Lake Forest, IL 60045

ES00N

Rev. 03/10

Principal Display Panel Text for Container Label:

NDC 17478-515-00

Ephedrine Sulfate

Injection, USP

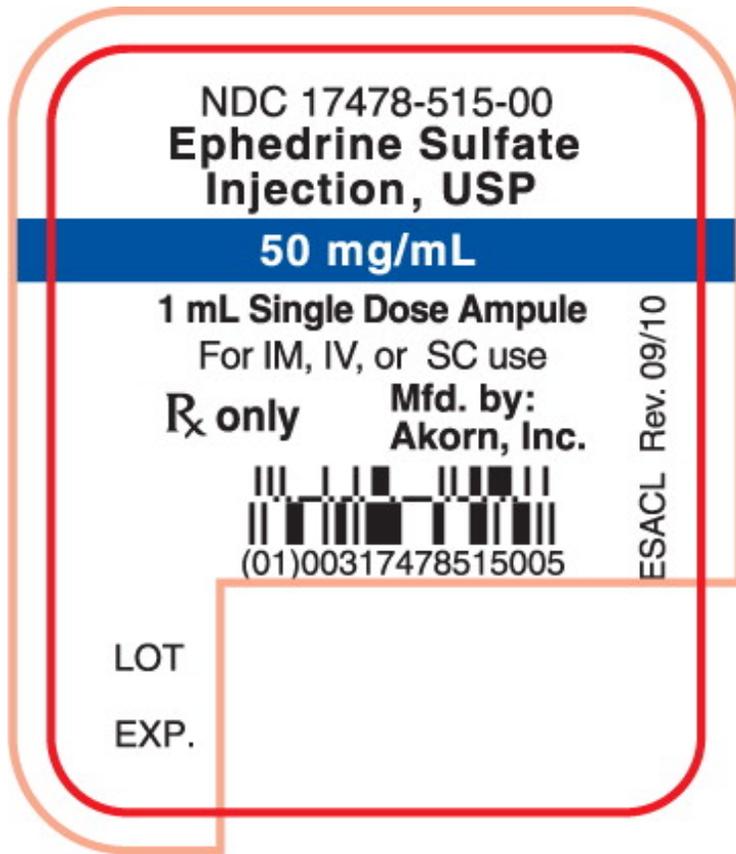
50 mg/mL

1 mL Single Dose Ampule

For IM, IV, or SC use

Mfd. by:

Rx only Akorn, Inc.



Principal Display Panel Text for Carton Label:

NDC 17478-515-00

Ephedrine Sulfate Injection, USP

50 mg/mL

For IM, IV, or SC use

1 mL Single Dose Ampules

10 Ampules (1 mL each)

Rx only Akorn

R_x only

Ephedrine Sulfate Injection, USP

50 mg/mL

10 Ampules (1 mL each)

Ephedrine Sulfate Injection, USP
50 mg/mL

NDC 17478-515-00

Ephedrine Sulfate Injection, USP

50 mg/mL

For IM, IV, or SC use

LOT

1 mL Single Dose Ampules
10 Ampules (1 mL each)

R_x only

Akorn

EXP.

R_x only

Ephedrine Sulfate Injection, USP

50 mg/mL

10 Ampules (1 mL each)

Each mL contains:
Active: Ephedrine Sulfate 50 mg
Inactive: Water for Injection.

Usual Dosage: See package insert for dosage information.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from light.



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 Lake Forest, IL 60045

ESACC Rev. 09/10



EPHEDRINE SULFATE

ephedrine sulfate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-515
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ephedrine Sulfate (UNII: U6X61U5ZEG) (Ephedrine - UNII:GN83C131XS)	Ephedrine Sulfate	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-515-00	10 in 1 CARTON	04/01/2009	
1		1 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2009	

Labeler - Akorn, Inc. (117696770)**Registrant** - Akorn Operating Company LLC (117693100)**Establishment**

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		117696832	MANUFACTURE(17478-515) , REPACK(17478-515) , ANALYSIS(17478-515) , LABEL(17478-515) , PACK(17478-515) , RELABEL(17478-515) , STERILIZE(17478-515)

Revised: 10/2020

Akorn, Inc.