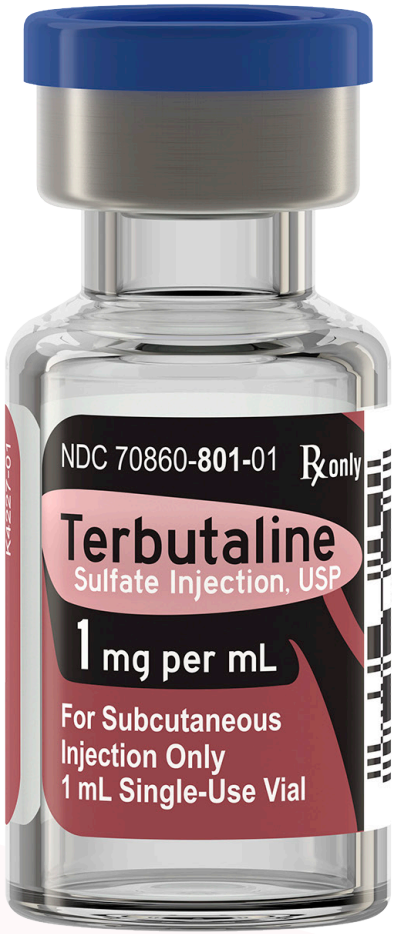
Terbutaline
Sulfate Injection, USP

1 mg per mL | NDC 70860-801-01



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- **BIG, BOLD AND BRIGHT —
TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT**
- **DIFFERENTIATION IN EVERY LABEL,
DESIGNED TO HELP REDUCE MEDICATION ERRORS**

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR TERBUTALINE SULFATE INJECTION, USP, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

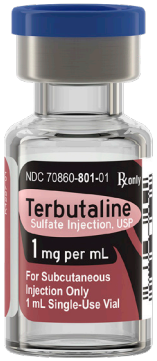
Terbutaline

Sulfate Injection, USP

1 mg

NDC 70860-801-01
1 mg per mL

DESCRIPTION	Glass Vial
CONCENTRATION	1 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 vials
BAR CODED	Yes



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Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

With a unique AccuraSEE label design for every Athenex product, we're helping your pharmacy to reduce the risk of medication errors. The idea is simple: "So what you see is *exactly* what you get."

Athenex

TERBUTALINE SULFATE Injection, USP

INDICATIONS AND USAGE

- Terbutaline sulfate injection is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

IMPORTANT SAFETY INFORMATION

WARNING: PROLONGED TOCOLYSIS

TERBUTALINE SULFATE HAS NOT BEEN APPROVED FOR AND SHOULD NOT BE USED FOR PROLONGED TOCOLYSIS (BEYOND 48 TO 72 HOURS). IN PARTICULAR, TERBUTALINE SULFATE SHOULD NOT BE USED FOR MAINTENANCE TOCOLYSIS IN THE OUTPATIENT OR HOME SETTING. SERIOUS ADVERSE REACTIONS, INCLUDING DEATH, HAVE BEEN REPORTED AFTER ADMINISTRATION OF TERBUTALINE SULFATE TO PREGNANT WOMEN. IN THE MOTHER, THESE ADVERSE REACTIONS INCLUDE INCREASED HEART RATE, TRANSIENT HYPERGLYCEMIA, HYPOKALEMIA, CARDIAC ARRHYTHMIAS, PULMONARY EDEMA AND MYOCARDIAL ISCHEMIA. INCREASED FETAL HEART RATE AND NEONATAL HYPOGLYCEMIA MAY OCCUR AS A RESULT OF MATERNAL ADMINISTRATION.

CONTRAINDICATIONS

- Prolonged Tocolysis- Terbutaline sulfate has not been approved for and should not be used for prolonged tocolysis (beyond 48 to 72 hours). In particular, terbutaline sulfate should not be used for maintenance tocolysis in the outpatient or home setting [see Boxed Warning, Prolonged Tocolysis]
- Hypersensitivity- Terbutaline sulfate injection is contraindicated in patients known to be hypersensitive to sympathomimetic amines or any component of this drug product.

WARNINGS

- Asthma may deteriorate acutely over a period of hours or chronically over several days or longer.
- The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids.
- Terbutaline sulfate should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Terbutaline sulfate can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. If these effects occur, the drug may need to be discontinued.
- There have been rare reports of seizures in patients receiving terbutaline; seizures did not recur in these patients after the drug was discontinued.

PRECAUTIONS

- Terbutaline, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, including ischemic heart disease, hypertension, and cardiac arrhythmias; in patients with hyperthyroidism or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines or who have convulsive disorders.
- Immediate hypersensitivity reactions and exacerbations of bronchospasm have been reported after terbutaline administration.
- Beta-adrenergic agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.
- Large doses of intravenous terbutaline have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis.
- Terbutaline sulfate should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.
- Terbutaline sulfate should be used during nursing only if the potential benefit justifies the possible risk to the newborn.

ADVERSE REACTIONS

- Common adverse reactions reported with terbutaline sulfate include tremor, nervousness, dizziness, headache, drowsiness, heart palpitations, tachycardia, dyspnea, chest discomfort, nausea, vomiting, weakness, flushed feeling, sweating, and pain at injection site.

OVERDOSAGE

- There is no specific antidote for terbutaline overdose. The expected symptoms with overdosage are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the adverse reactions listed above.
- Treatment consists of discontinuation of terbutaline sulfate injection together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm.
- There is insufficient evidence to determine if dialysis is beneficial for overdosage of terbutaline sulfate injection.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for TERBUTALINE SUFLATE Injection, USP.