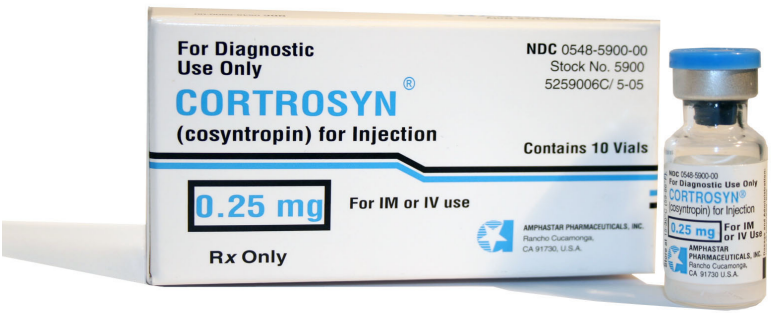
from

Amphastar Pharmaceuticals, Inc.

Reliable Diagnosis *of* Adrenocortical Insufficiency



Wholesaler Item Numbers

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AMPHASTAR PHARMACEUTICALS, INC.
11570 Sixth St., Rancho Cucamonga, CA 91730 | visit us online at **www.Amphastar.com**
For more Information, Please call **1-800-423-4136** | Fax: **(909) 980-5726**

- **For IM or I.V. use**
- **Single Source (non-AB-rated):** non-substitutable unless authorized by prescriber
- **Fast:** may be used to perfrm a 30-minute test of adrenal function
- **Convenient:** no refrigeration required
- **Flexible:** can be used in office based or outpatient procedures

Cortrosyn®

(cosyntropin for injection)

Contains 0.25 mg of Cortrosyn®

NDC# 0548-5900-00 **Rx Only**

For more information or to place and order, please call **1-800-423-4136**

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(cosyntropin for injection)

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DESCRIPTION

CORTROSYN® (cosyntropin for injection) is a sterile lyophilized powder in vials containing 0.25 mg of CORTROSYN® and 10 mg of mannitol to be reconstituted with 1 mL of 0.9% Sodium Chloride Injection, USP. Administration is by intravenous or intramuscular injection. Cosyntropin is α 1 -24 corticotropin, a synthetic subunit of ACTH. It is an open chain polypeptide containing, from the N terminus, the first 24 of the 39 amino acids of natural ACTH.

INDICATIONS AND USAGE

CORTROSYN® is intended for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency. Because of its rapid effect on the adrenal cortex it may be utilized to perform a 30-minute test of adrenal function (plasma cortisol response) as an office or outpatient procedure, using only 2 venipunctures.

CONTRAINDICATION

The only contraindication to CORTROSYN® is a history of a previous adverse reaction to it.

PRECAUTIONS

General

CORTROSYN® exhibits slight immunologic activity, does not contain animal protein and is therefore less risky to use than natural ACTH. Patients known to be sensitized to natural ACTH with markedly positive skin tests will, with few exceptions, react negatively when tested intradermally with CORTROSYN®. Most patients with a history of a previous hypersensitivity reaction to natural ACTH or a pre-existing allergic disease will tolerate CORTROSYN®. Despite this however, CORTROSYN® is not completely devoid of immunologic activity and hypersensitivity reactions including rare anaphylaxis are possible. Therefore, the physician should be prepared, prior to injection, to treat any possible acute hypersensitivity reaction.

Drug Interactions

Corticotropin may accentuate the electrolyte loss associated with diuretic therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential or impairment of fertility. A study in rats noted inhibition of reproductive function like natural ACTH.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with CORTROSYN®. It is also not known whether CORTROSYN® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CORTROSYN® should be given to a pregnant woman only if clearly needed.

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Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CORTROSYN® is administered to a nursing woman.

Pediatric Use

(See package insert for prescribing information.)

ADVERSE REACTIONS

Since CORTROSYN® is intended for diagnostic and not therapeutic use, adverse reactions other than a rare hypersensitivity reaction are not anticipated. A rare hypersensitivity reaction usually associated with a pre-existing allergic disease and/or a previous reaction to natural ACTH is possible. Symptoms may include slight whealing with splotchy erythema injection site. There have been rare reports of anaphylactic reaction. The following adverse reactions have been reported in patients after the administration of CORTROSYN® and the association has been neither confirmed nor refuted: bradycardia; tachycardia; hypertension; peripheral edema; and rash.

A paradoxical response may be noted in the cortisone or hydrocortisone group as seen in a decrease in plasma cortisol values following a stimulating dose of CORTROSYN®. In the spironolactone or estrogen group only a normal incremental response is to be expected. Many patients with normal adrenal function, however, do not respond to the expected degree so that the following criteria have been established to denote a normal response:

1. The control plasma cortisol level should exceed 5 mcg/100 mL.
2. The 30-minute level should show an increment of at least 7mcg/100 mL above the basal level.
3. The 30-minute level should exceed 18 mcg/100 mL. Comparable figures have been reported by Greig and co-workers.

Plasma cortisol levels usually peak about 45 to 60 minutes after an injection of CORTROSYN® and some prefer the 60-minute interval for testing for this reason. While it is true that the 60-minute values are usually higher than the 30-minute values, the difference may not be significant enough in most cases to outweigh the disadvantage of a longer testing period. If the 60-minute test period is used, the criterion for a normal response is an approximate doubling of the basal plasma cortisol value. In patients with a raised plasma bilirubin or in patients where the plasma contains free hemoglobin, falsely high fluorescence measurements will result. The test may be performed at any time during the day but because of the physiological diurnal variation of plasma cortisol the criteria listed by Wood cannot apply. It has been shown that basal plasma cortisol levels and the post CORTROSYN® increment exhibit diurnal changes. However, the 30-minute plasma cortisol level remains unchanged throughout the day so that only this single criterion should be used (3). Parenteral drug products should be inspected visually for particulate matter and discoloration whenever solution and container permit. Reconstituted CORTROSYN® should not be retained.

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