ALLERGENIC EXTRACT

Prescription Set of Serial Dilutions (or Maintenance Vial (s))

INSTRUCTIONS FOR USE

U.S. Government License No. 308

GREER™
PO Box 800
Lenoir, NC 28645
USA

Revised 07/04

DESCRIPTION

This set consists of multiple vials of one or more premixed allergenic extracts, diluted according to a specified formula with sterile buffered saline, or glycero-saline, and containing 0.4% phenol preservative. Contents of each vial have been tested to assure sterility and lack of abnormal toxicity.

CLINICAL PHARMACOLOGY

Although clinical studies have shown an increase of IgG blocking antibody with administration of allergenic extracts, the total mechanism is not yet known and is still being investigated.

INDICATIONS

Hyposensitization is indicated when careful testing and patient history can pinpoint allergens responsible for allergic symptoms, and when it is not possible or practical to avoid these allergens. Allergenic extracts are administered to reduce symptoms of allergy of a seasonal or perennial nature.

CONTRADICTIONS

Although there are no known contraindications, initiating therapy during pregnancy or in infants under the age of two is not advised. If the offending substance or substances can be successfully removed from the environment, therapy is not considered necessary. Immunotherapy with specific antigens is indicated only when individuals have been shown to be skin sensitive to those specific antigens.

WARNINGS

Allergenic extracts may vary in potency from lot to lot. Comparative skin testing using equal concentrations of the old and new lots can be used to assess relative potency. Marked differences in skin reactivity will indicate differences in potency and the need to adjust dosages so as to avoid a possible adverse reaction. When a new vial of fresher material is being injected, dosage should be reduced by at least one half to allow for the increased potency of the fresher material. When the patient is beginning injections from a new lot, careful observation should be made of any undue reaction from the injection. Should a reaction occur, the next injection should not be increased, but held at the same level or slightly reduced. Repeat this dosage until no reaction occurs. Any person administering a biological product should be aware of the risk of general or systemic reaction if improperly used. Allergenic extracts should be administered only by persons knowledgeable in recognizing a generalized or constitutional reaction and capable of handing such reactions.

PRECAUTIONS

Check lot number and dosage schedule of patient to verify correctness of prescription number and vial number. Only after this verification has been made should an appropriate injection be given. A separate sterile needle and syringe should be used for each patient to prevent transmission of homologous serum hepatitis and other infectious agents.

Inject subcutaneously in the lateral aspect of the upper arm of the thigh, being careful to avoid injecting into a blood vessel of vein. Use a 26 or 27 gauge needle 3/8" in length for injection. Beginning dosages, before maintenance levels are reached, may be given twice weekly until maintenance level is reached, allowing 2 to 7 days between injections, and using alternate injection sites. When maintenance or strongest dosage is reached, injections can normally be given once weekly or biweekly.

Keep the patient under direct observation for at least 20 minutes after each injection so that any evidence of a general of constitutional reaction can be noted and properly handled. The patient should be advised to inform the physician in the event of any type of delayed reaction.

PREGNANCY

PREGNANCY CATEGORY C - Animal reproduction studies have not been conducted with allergenic extracts. It is also not known whether allergenic extracts can cause fetal harm when administered to a pregnant woman or whether they can affect reproductive capacity.

ADVERSE REACTIONS

Allergic reactions following injections of allergens include generalized erythema, pruritis, rhinitis, asthma, and laryngeal edema. Syncope, shock, and hypotension have also been reported.

Adverse reactions should be treated as follows:

A. A tourniquet should be immediately applied to the extremity above the site of injection. Release tourniquet every few minutes for a few seconds.

B. Epinephrine 1:1000 should be injected immediately in the opposite arm in amounts of 0.3 to 0.5 mL and 0.2 mL epinephrine should be administered at the site of injection. For children below the age of 6 years, adjust dosage of epinephrine to .005 mL per pound of body weight per dose. Repeat epinephrine dosage in 15 minutes if necessary and if symptoms persist.

C. Adverse reactions not responding to epinephrine therapy may require the use of parenteral bronchodilators, vasopressors, oxygen, or volume replacement therapy.

If any significant local reaction occurs after an injection, the next scheduled dose should be reduced by 0.1 to 0.2 mL before attempting any increase in dosage.

For those patients with severe reactions, allow a minimum of 24 hours after all reactions have subsided before giving the next injection. Reduce the dosage by one half and make dosage increases more gradually. After a severe reaction occurs, do not increase dosage if any local reaction occurs. For continuing reactions, a weaker dilution should be used. Some patients are more sensitive and will not be able to tolerate the dosage achieved by less sensitive patients.

OVERDOSAGE

Systemic reactions are uncommon after injection, but if the patient receives more extract that can be tolerated at that particular time (see Adverse Reactions), the following procedures should be instituted:

1. Apply tourniquet above the site of injection.
2. Administer epinephrine.
3. Adverse reactions not responding to epinephrine therapy may require the use of parenteral bronchodilators, vasopressors, oxygen, or volume replacement therapy.

Overdosage may occur because of an error in the volume of extract injected, an incorrect dilution injected, or because the patient may be exposed to airborne antigens simultaneously with injection of the same antigens. In the event of systemic reaction occurring, the dosage schedule should be carefully reviewed, as well as environmental conditions to which the patient is exposed. Subsequent dosage should be reduced to a level where no reaction occurs, and increased more gradually than initial scheduling suggests.

DOSAGE AND ADMINISTRATION

Initial and subsequent dosage is based on careful testing procedures and patient history. Very sensitive patients must be started on lower concentrations than those with only moderate sensitivities, and must be brought up to full or maintenance dosage more gradually. Very sensitive patients should start with highly dilute extract, under the level which elicits a positive reaction form intradermal testing.

For mixtures containing Short Ragweed, please refer to Ragweed package Insert enclosed with this shipment.

For patients of moderate sensitivity, see suggested dosage schedules (next page). Since patients exhibit large variations in sensitivity, these schedules should be modified by the physician to suit the individual patient.

SUGGESTED DOSAGE SCHEDULE *
FOR MODERATELY SENSITIVE PATIENT

On Weight by Volume Standard

Dosage No.	Dilution	Vol. in mL	Bottle No.
1	1:10,000	0.05	1
2	1:10,000	0.10	1
3	1:10,000	0.20	1
4	1:10,000	0.40	1
5	1:10,000	0.70	1
6	1:1,000	0.10	2
7	1:1,000	0.20	2
8	1:1,000	0.30	2
9	1:1,000	0.50	2
10	1:1,000	0.70	2
11	1:100	0.10	3
12	1:100	0.15	3
13	1:100	0.20	3
14	1:100	0.30	3
15	1:100	0.40	3
16	1:100	0.50**	3

On P.N. Unit Standard

Dosage No.	P.N. Unit per mL	Vol. in mL	Bottle No.
1	100	0.05	1
2	100	0.10	1
3	100	0.20	1
4	100	0.40	1
5	100	0.70	1
6	1,000	0.10	2
7	1,000	0.20	2
8	1,000	0.30	2
9	1,000	0.50	2
10	1,000	0.70	2
11	10,000	0.10	3
12	10,000	0.15	3
13	10,000	0.20	3
14	10,000	0.30	3
15	10,000	0.40	3
16	10,000	0.50	3

*To be modified by the physician to suit the individual patient.
**Maintenance Dosage

Prescription sets are supplied as a set of 5 or 10 mL vials of graduated dilutions, consisting of 4 or more vials of differing concentrations. Vial #1 contains the weakest dilution, Vial #4 (or #5 or #6) contains the strongest concentration or maintenance dosage. Treatment sets are supplied on either the basis of weight in volume dilution, or based on the protein nitrogen unitage dilution. A typical weight to volume set may consist of 4 vials of 1:100,000, 1:10,000, 1:1,000 and maintenance vial(s) of 1:100 W/V. A typical treatment set based on protein nitrogen unitage may consist of 4 vials of 10 PNU/mL, 100 PNU/mL, 1,000 PNU/mL and 10,000 PNU/mL.

STORAGE

Allergenic extracts should be stored at 2°-8°C.