

have discontinued the ad in question and all future ads will carry the new "Brief Summary".

The safety and efficacy of Diutensen-R are not in question when used in accordance with the prescribing information in the official package insert.

Sincerely,

NEISLER LABORATORIES.

(NOTE: This revised "Brief Summary," for use in future medical journal advertising, contains additional words and phrases (printed in capital letters) taken from the official package insert.)

BRIEF SUMMARY OF WARNING INFORMATION FOR DIUTENSEN-R

(For prescribing information, consult official package insert)

Indications: Hypertension.

Contraindications: SEVERE DEPRESSION and KNOWN HYPERTENSIVITY TO reserpine, VERATRUM VIRIDE OR THIAZIDE COMPOUNDS.

WARNING: WITH THE ADMINISTRATION OF ENTERIC-COATED POTASSIUM SUPPLEMENTS, WHICH SHOULD BE USED ONLY WHEN ADEQUATE DIETARY SUPPLEMENTATION IS NOT PRACTICAL, THE POSSIBILITY OF SMALL BOWEL LESIONS CONSISTING OF STENOSIS WITH OR WITHOUT ULCERATION, AND CAUSING OBSTRUCTION, HEMMORRHAGE, AND PERFORATION, SHOULD BE KEPT IN MIND. SURGERY FOR THESE LESIONS HAS FREQUENTLY BEEN REQUIRED AND DEATHS HAVE OCCURRED. DISCONTINUE COATED POTASSIUM-CONTAINING FORMULATIONS IMMEDIATELY IF ABDOMINAL PAIN, DISTENTION, NAUSEA, VOMITING, OR GASTROINTESTINAL BLEEDING OCCUR.

DISCONTINUE 2 WEEKS BEFORE GENERAL ANESTHESIA OR ELECTROSHOCK THERAPY, AND IF DEPRESSION OR PEPTIC ULCER OCCURS.

Precautions: ELECTROLYTE IMBALANCE, HYPOCHLOREMIC ALKALOSIS SODIUM AND/OR POTASSIUM DEPLETION MAY OCCUR. IF POTASSIUM DEPLETION SHOULD OCCUR DURING THERAPY, DIUTENSEN-R SHOULD BE DISCONTINUED AND POTASSIUM SUPPLEMENTS GIVEN, PROVIDED THE PATIENT DOES NOT HAVE MARKED OLIGURIA. HYPOCHLOREMIC ALKALOSIS MAY BE TREATED WITH AMMONIUM CHLORIDE IF NO LIVER DISEASE IS PRESENT.

PARTICULAR OBSERVANCE OF THE SERUM ELECTROLYTE BALANCE AND/OR POTASSIUM SUPPLEMENTATION IS NECESSARY IN PATIENTS RECEIVING HIGHER DOSAGE LEVELS, DIGITALIS, POTASSIUM DEPLETING CORTICOSTEROIDS, AND IN CIRRHOSIS ESPECIALLY WHEN THERE IS IMPENDING HEPATIC COMA.

IF PROGRESSIVE INCREASE IN SERUM NITROGEN (BUN, NPN, OR CREATININE) OCCURS, THERAPY SHOULD BE DISCONTINUED.

USE WITH CAUTION IN PATIENTS WITH A HISTORY OF PEPTIC ULCER, ULCERATIVE COLITIS, OR DEPRESSION.

DIUTENSEN-R MAY INCREASE THE POSSIBILITY OF DIGITALIS INTOXICATION. Reduce dose or discontinue if myocardial irritability occurs (extrasystoles, bigeminy or AV block).

Adverse Reactions: Occasional urinary frequency, nocturia, nasal congestion, DRYNESS OF THE MOUTH, muscle cramps, skin rash, joint pains due to gout, nausea, VOMITING, and dizziness.

POTENTIAL SIDE EFFECTS INCLUDE HYPERGLYCEMIA, RISE IN SERUM URIC ACID, PURPURA, THROMBOCYTOPENIA, LEUKOPENIA, PARKINSONISM, BRADYCARDIA AND EXCESSIVE HYPOTENSION WITH PROSTRATION. (TREAT BRADYCARDIA WITH ATROPINE AND HYPOTENSION WITH VASOPRESSORS.) DRUG SHOULD BE DISCONTINUED IF SUFFICIENT HYPERGLYCEMIA IS OBSERVED, OR IF PURPURA, THROMBOCYTOPENIA, OR LEUKOPENIA OCCUR.

Usual Dosage: One tablet twice daily at morning and evening meals. Daily dosage should not exceed 4 tablets.

WORCESTER, MASS., August 23, 1967.

DEAR DOCTOR: The Food and Drug Administration has asked us to call to your attention two of our recent mailing pieces for Citanest® which the FDA regards as so substantially misleading and lacking in adequate professional use information that in its view they represent potential hazards to health