SOMATONORM 4 IU ▼

PRESCRIBING INFORMATION

PRESENTATION

A vial of sterile lyophilised powder of somatrem corresponding to 4 IU of human somatotropin (also containing aminoacetic acid and sodium phosphate as stabilisers) and supplied with a 2 ml ampoule of water for injections for use in the reconstitution of the injection.

USES

The treatment of short stature caused by decreased or absent secretion of pituitary growth hormone. The diagnosis should be verified by appropriate investigations of pituitary function by a specialist medical practitioner.

DOSAGE AND ADMINISTRATION

Route of administration:

By intramuscular injection.

Recommended dosage:

The dosage should be calculated according to patient's body weight. Generally a dose of 5 IU/kg body weight per week is recommend. This weekly dose should be divided into 2 3 intramuscular injections.

EPARATION OF SOLUTION

e solution is prepared by adding 2 ml of ater for injections to the lyophilised sub-

ance in the vial. Gently dissolve the drug with slow swirling motion. Do not shake vigously as this may cause denaturation of the tive ingredient.

CNTRA-INDICATIONS, WARNINGS, ETC.

inly patients with unfused epiphyses should e treated. Diabetes mellitus.

Arecautions.

Patients treated with Somatonorm should be regularly assessed by a specialist in child growth. This assessment should include determination of growth response and endocrinological status, as relative deficiencies of other pituitary hormones may be exposed or exacerbated by an adequate growth response.

Acute overdosage is unlikely and does not represent a hazard to the patient. The consequences of long term administration of doses above the normal therapeutic range are unknown.

Side-effects:

Clinical experience with Somatonorm is limited and recipients may develop antibody to growth hormone and E. coli protein. However, as with pituitary derived hormone, only in very rare instances has growth retardation occurred. No other adverse reactions have been noted.

PHARMACEUTICAL PRECAUTIONS

Store at 2-8°C. Reconstituted Somatonorm may be stored in the refrigerator for 24 hours before use.

LEGAL CATEGORY POM

PACKAGE QUANTITIES

Combined package containing one vial of somatrem 4 IU and one ampoule of 2 ml water for injections.

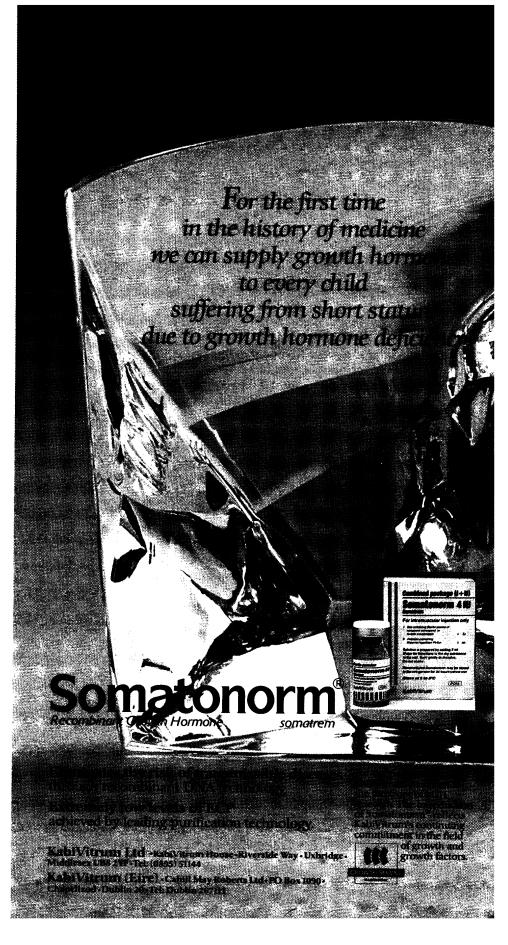
FURTHER INFORMATION

Somatonorm is produced using recombinant DNA technology. Somatrem is the British Approved Name for methionyl human somatotropin.

PRODUCT LICENCE NUMBER

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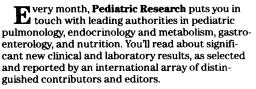
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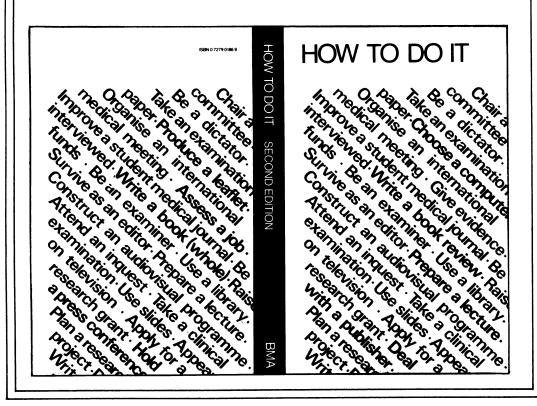
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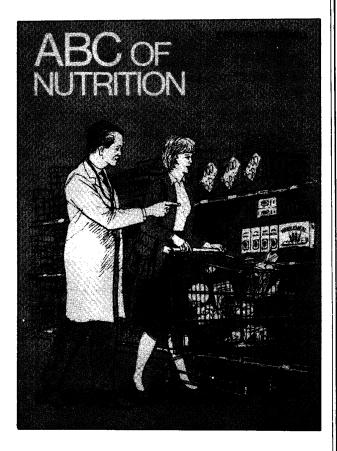
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