#### 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 the patient's body weight. Generally a dose of 0.5 IU/kg body weight per week is recommended. This weekly dose should be divided into 2 or 3 intramuscular injections.

#### PREPARATION OF SOLUTION

The solution is prepared by adding 2 ml of water for injections to the lyophilised substance in the vial. Gently dissolve the drug with a slow swirling motion. Do not shake vigorously as this may cause denaturation of the active ingredient.

#### CONTRA-INDICATIONS, WARNINGS, ETC.

Only patients with unfused epiphyses should be treated. Diabetes mellitus.

#### Precautions:

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.

#### Overdosage:

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  $2-8^{\circ}C$ . 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

0022/0060

P.A. 187/28/1

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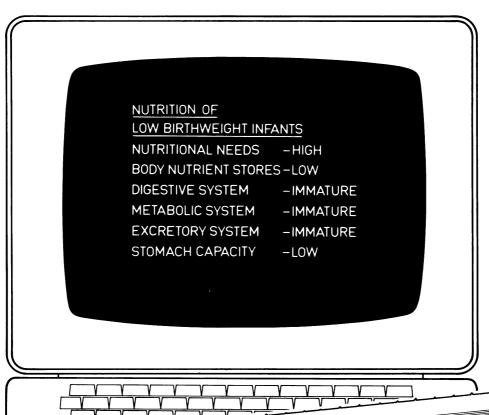
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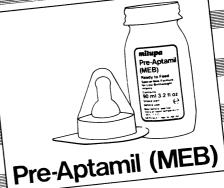


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1. Brooke, O. G., Wood, C., Barley, J. Arch. Dis. Child 1982, **57,** 898–904.

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### Volume 145 Number 1-2 April 1986

The pioneers of pediatric medicine 1

#### Editorial

Burgio: Sir Garrod's 'Inborn Errors of Metabolism' and 'Chemical Individuality' 2

#### Annotation

Laron and Baumann: Growth hormone releasing hormone 6

#### Original investigations

Triadou et al.: Neocytopheresis in thalassaemia major 10

Janka-Schaub et al.: Intermediate-dose methotrexate in acute lymphocytic leukaemia 14

Grønn et al.: C-reactive protein in infections of the immunosuppressed child 18

Ishii et al.: Protein phosphorylation of neutrophils in chronic granulomatous disease 22

Kruse and Kracht: Serum osteocalcin as an index of altered bone metabolism 27

Stöß et al.: Heterogeneity of osteogenesis imperfecta 34

Rosenberg and Löhr: A new hereditary bone dysplasia 40

Clayton et al.: Mischandrial phosphosplaywayte carbovykings

Clayton et al.: Mitochondrial phosphoenolpyruvate carboxykinase deficiency 46

De Luca et al.: Prenatal exclusion of purine nucleoside phosphorylase deficiency 51

Tazawa et al.: Lipoprotein-X and gammaglutamyltranspeptidase in biliary atresia 54

Den Ouden et al.: Scarring of the hands from venipunctures in babies 58

Mulder and Zanen: Listeria monocytogenes neonatal meningitis 6 lwai et al.: Iron status in low birth weight infants on breast and formula feeding 63

Van Acker et al.: Haemorrhagic shock and encephalopathy 60 Lanes et al.: Pituitary-thyroidal axis in newborns undergoing exchange transfusion 70

de Beaufort et al.: Overnight metabolic profiles in very young diabetic children 73

De Luca et al.: Thyroid function tests and carbamazepine in hypothyroid children 77

Schöni et al.: Dopamine-beta-hydroxylase in patients with cystic fibrosis 80

Larizza et al.: Difficult hGH treatment in type III glycogen storage disease 84

Fennell et al.: Statural growth following kidney transplantation 86

Variend and Howat: Renal glomerular size in CHD and in sudden infant death  $\phantom{0}$  90  $\phantom{0}$ 

Deutsch et al.: Epstein-Barr virus DNA in fulminant hepatic failure 94

Mayumi et al.: Immunoglobulin M deficiency and disseminated molluscum contagiosum  $\phantom{0}99\phantom{0}$ 

Furukawa et al.: Polyclonal B cell activation in mucocutaneous lymph node syndrome 104

Koletzko et al.: Fatty acid composition of plasma lipids in proteinenergy malnutrition 109

Trowitsch et al.: Severe pulmonary arterial stenoses in Conradi-Hünermann disease 116

Sumer et al.: Severe congenital factor X deficiency with intracranial haemorrhage 119

Tsukahara et al.: Ataxia telangiectasia, skin pigmentation and early death 121

Laufer et al.: Anuria in a premature infant due to ureteropelvic fungal bezoar 125

#### Short communications

Eiholzer et al.: Recovery from post-traumatic anterior pituitary insufficiency 128

Leiberman et al.: Low grade mucoepidermoid tumour of the bronchus 130

Zamboni et al.: Parathyroid hormone, calcitonin and vitamin D metabolites in beta-thalassaemia major 133

Wanders et al.: Prenatal test for Zellweger syndrome 136
Ashkenazi et al.: Effect of splenectomy on destructive bone changes in Gaucher disease 138

#### Case reports

Wales et al.: Partial trisomy 11 - bronze baby - biliary hypoplasia - Wiedemann-Beckwith syndrome 141

Wit et al.: Thyroid-stimulating immunoglobulins and thyroid function tests in neonatal thyrotoxicosis 143

Hadjilambris: True precocious puberty and CNS-hamartoma 148
Shuper et al.: Dubowitz Syndrome in the neonatal period 151
Muis et al.: Aase syndrome 153

Letters to the editors 157

Indexed in Current Contents

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# Monatsschrift Kinder- Organ der Deutschen Gesellschaft für Kinderheilkunde heilkunde

## 134. Band Heft 4 April 1986

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	Thema des Monats Immuntherapie bei Viruserkrankungen	This Month's Topic Immunotherapy in Viral Diseases	171
H. Schulte-Wissermann, O. Schofer	Immuntherapie bei Viruserkrankungen	Immunotherapy in Viral Diseases	172
	Pädiatrie aktuell	Trends in Paediatrics	182
	Was hat das Kind?	What's Wrong with the Child?	
neu	Trainingsprogramm für die Weiterbildung zum Kinderarzt	Program for Continuing Education of Paediatricians	183
	Aus Klinik und Forschung Originalien	Clinic and Research Originals	
H. H. Kramer, B. Hendrikx, H. J. Trampisch, M. Krüger	Elterngröße und kindliche Größenentwick- lung	Parental Height and Children's Growth Development	184
A. Hussein, H. von der Hardt, W. Müller, S. M. Schell	Intravenöse Infusion von Reproterol (ein Beta-2-Mimetikum) in der Therapie des schweren Asthma-Anfalls im Kindesalter	Intravenous Infusion of Reproterol (a Beta- 2-Adrenergic Agent) in the Treatment of Acute Severe Asthma in Children	192
K. E. Bonzel, O. Mehls, D. E. Müller- Wiefel, L. Diekmann, R. Wartha, H. Ruder, W. Rascher, K. Schärer	Kontinuierliche ambulante Peritoneal- dialyse (CAPD) bei Kindern und Jugend- lichen	Continuous Ambulatory Peritoneal Dialysis (CAPD) in Children and Adolescents	197
L. Gortner, F. Pohlandt	Der interessante Fall Austauschtransfusion über einen peri- pheren arterio-venösen Gefäßzugang bei Frühgeborenen	Interesting Cases Peripheral Arteries and Veins for Exchange Transfusion in Very Low Birthweight Infants	205
H. Steigenberger	Transitorischer Diabetes mellitus des Neu- geborenen	Transient Diabetes Mellitus in the Newborn	207
W. Beck, P. Stubbe	Verlaufsbeobachtung eines kindlichen Prolaktinproduzierenden Hypophysentumors	Follow-up Study of a Prolactin-Producing Pituitary Tumor in an Adolescent	209
Th. Bömelburg, C. Ehringhaus, R. Ziegler, HJ. von Lengerke, C. Timm	Hüftkopfnekrose bei Sichelzellanämie	Caput Femoris Necrosis in Sickle Cell Anemia	212
	Wußten Sie schon? Neues aus Therapie und Prophylaxe	Do You Know? New Developments in Therapy and Prophylaxis	
HJ. Radü	Das Diagnoseproblem: Hörstörungen im Kindesalter	Hearing Loss as a Diagnostic Problem in Children	216
	Auflösung und Kommentar des Trainings- programms für die Weiterbildung zum Kinderarzt	Solution and Commentary in the Program for Continuing Education of Paediatricians	219
	Neue Bücher	New Books	220
	Tagesgeschichte, Personalia	News of the Day, Personal News	221
	Tagungskalender	Forthcoming Meetings	221
	Für die Dokumentation	Documentation	A 64

Indexed in Current Contents

Monatsschr Kinderheilkd (1986) 134, 4

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