

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 2ml 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°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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Abbreviated Prescribing Information

'HUMULIN' S ▼ 'HUMULIN' I ▼
'HUMULIN' Zn ▼ 'HUMULIN' M1 ▼
'HUMULIN' M2 ▼ Human insulin (crb)

Presentation: Humulin S: A sterile, aqueous solution of human insulin (crb). Humulin I: A sterile suspension of isophane human insulin (crb). Humulin Zn: A sterile suspension of crystalline human insulin (crb) zinc suspension.

Humulin M1: A sterile suspension of human insulin (crb) in the proportion of 10% soluble insulin and 90% isophane insulin. **Humulin M2:** A sterile suspension of human insulin (crb) in the proportion of 20% soluble insulin and 80% isophane insulin. Each presentation contains 100 IU/ml. **Uses:** For the treatment of insulin-dependent diabetes mellitus.

Dosage and Administration: The dosage should be determined by the physician, according to the requirements of the patient. Humulin S may be administered by subcutaneous, intramuscular or intravenous injection. Humulin I, Humulin Zn, Humulin M1 and Humulin M2 should be administered by subcutaneous or intramuscular injection only. Humulin S may be administered in combination with Humulin I or Humulin Zn as required. **Humulin I, Zn, M1 and M2:** Rotate vial in palms of hands immediately before use to re-suspend. **Mixing of insulins:** The shorter-acting insulin should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting preparation. It is advisable to inject immediately after mixing. **Contra-indications, Warnings, etc. Contra-indications:**

Hypoglycaemia. Under no circumstances should Humulin I, Humulin Zn, Humulin M1 or Humulin M2 be given intravenously. **Precautions: Usage in pregnancy:** Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. **Transferring from other insulins:** A small number of patients transferring from insulins of animal origin may require a reduced dosage and/or a change in the ratio of soluble to intermediate preparations, especially if they are very tightly controlled and bordering on hypoglycaemia. The risk of hypoglycaemia can be considered minimal if the daily dosage is less than 40 IU. Insulin-resistant patients receiving more than 100 IU daily should be referred to hospital for transfer. **Side-effects:** Lipodystrophy, insulin resistance and hypersensitivity have rarely been reported. **Legal Category:** P. **Package Quantities:** 10ml glass vials in packs of 5. **Price:** Humulin S: 100 IU/ml. £6.68; Humulin I: 100 IU/ml. £6.68; Humulin Zn: 100 IU/ml. £6.68; Humulin M1: 100 IU/ml. £6.68; Humulin M2: 100 IU/ml. £6.68. **Product Licence Numbers, Name and Address:** Humulin S 100 IU/ml 0006/0165 Humulin I 100 IU/ml 0006/0168 Humulin Zn 100 IU/ml 0006/0179 Humulin M1 100 IU/ml 0006/0199 Humulin M2 100 IU/ml 0006/0200. **Date of Preparation:** January 1986.

References: 1. Corcoran, J.S. and Yudkin, J.S. *Diabetic Medicine*, 1985, 2, 131-133. 2. Fineberg, S.E. *et al. Diabetologia*, 1983, 25, 465-469.

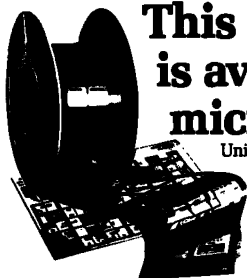
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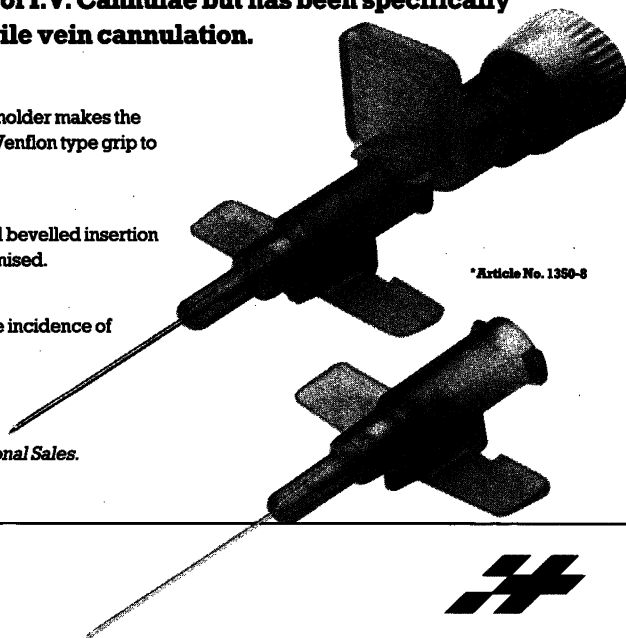
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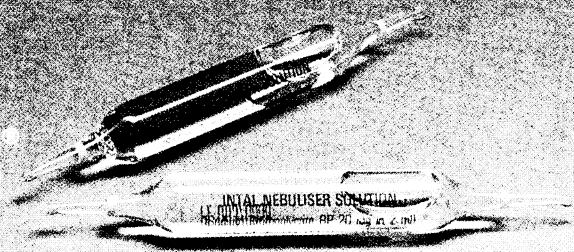
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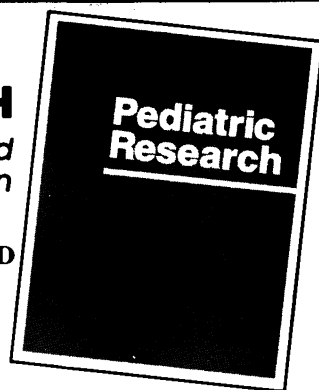
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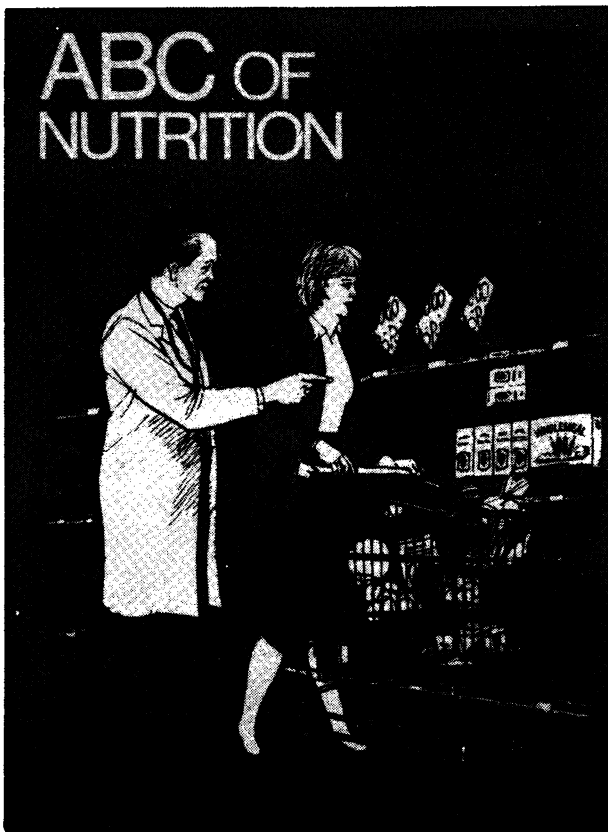
	Thema des Monats	This Month's Topic	
	Atriales natriuretisches Peptid – Ontogenese des Immunsystems	Atrial Natriuretic Peptide – Ontogeny of the Immune System	709
T. Tulassey, W. Rascher	Atriales natriuretisches Peptid	Atrial Natriuretic Peptide	710
H. Schneider	Zur Ontogenese des Immunsystems	The Ontogeny of the Immune System	716
	Pädiatrie aktuell	Trends in Paediatrics	723
	Was hat des Kind?	What's Wrong with the Child?	
	Trainingsprogramm für die Weiterbildung zum Kinderarzt	Program for Continuing Education of Paediatricians	724
	Aus Klinik und Forschung Originalien	Clinic and Research Originals	
S. Nolte, W. Pringsheim, W. Künzer	β_2 -Mikroglobulin im Serum als Parameter der glomerulären Nierenfunktion in den ersten Lebenstagen	β_2 -Microglobulin – a Parameter of Glomerular Renal Function in the First Days of Life	725
J. Sander, Ch. Niehaus	Ergebnisse einer Pilotstudie für ein Neugeborenen- Screening auf angeborenen Biotinidasemangel	Newborn Screening for Congenital Biotinidase Deficiency. Results of a Pilot Study	729
H. Helwig, P. Schlegel	Cefotaxim Monotherapie der bakteriellen Meningitis im Kindesalter	Cefotaxim Monotherapy in Bacterial Meningitis of Childhood	733
K. H. Deeg, F. Bundscherer, B. Böwing	Zerebrale Ultraschalldiagnostik bei Hirnmißbildungen	Cerebral Ultrasonography in Cerebral Malformations	738
	Der Interessante Fall	Interesting Cases	
R. Behrens, M. Rey, H. P. Hümmer, K. Stehr	Ein ungewöhnlicher Fall von Invagination	An Unusual Case of Intussusception	748
C. Ehringhaus, H. Chr. Dominick, K.-D. Bachmann	Minderwuchs und Dystrophie bei Morbus Crohn	Growth Failure and Dystrophy in Crohn's Disease During Childhood	751
D. Menzel, L. Monnens	Osteogenesis imperfecta Typ III assoziiert mit hypophosphatämischer, Vitamin D-resistenter Rachitis	Osteogenesis Imperfecta Type III, Associated with Hypophosphatemic Vitamin D-Resistant Rickets	755
	Wußten Sie schon?	Do You Know?	
D. Penn, H. Schmidt, A. Otten, E. Schmidt-Sommerfeld	<i>Neues aus Therapie und Prophylaxe</i> Carnitin in der Behandlung der Methyl- malonazidurie (MMA)	<i>New Developments in Therapy and Prophylaxis</i> L-Carnitine Therapy in Methylmalonic Aciduria	758
V. Weidman, P. Allhoff	<i>Aus der Praxis – für die Praxis</i> Wachstumskurven als Screeninginstrument – Möglichkeiten und Grenzen	<i>Practical Tips for Practitioners</i> Growth-Charts as a Tool for Screening – Advantages and Limitations	761
D. Schuler, J. Borsi, R. Koós, T. Révész, G. Kardos, P. Somló	<i>Aus der Klinik – für die Klinik</i> Neue Aspekte der Methotrexat-Blutspiegel- bestimmung bei leukämischen Kindern	<i>Practical Tips for Clinicians</i> New Aspects of the Determination of MTX Serum Concentration in Children Suffering from ALL	765
	Auflösung und Kommentar des Trainings- programms für die Weiterbildung zum Kinderarzt	Solution and Commentary in the Program for Continuing Education of Paediatricians	769
W. Ch. Hecker	In memoriam Prof. Dr. Anton Oberniedermayr	In memoriam Prof. Dr. Anton Oberniedermayr	768
	Tagesgeschichte, Personalia	News of the Day, Personal News	770
	Tagungskalender	Forthcoming Meetings	770
	Für die Dokumentation	Documentation	A 54

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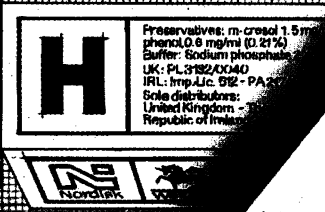
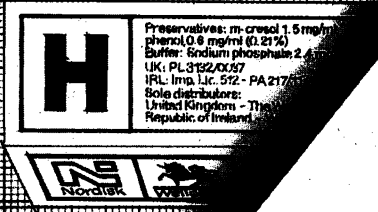
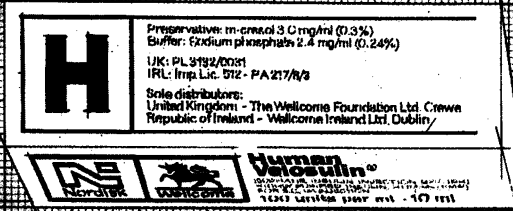
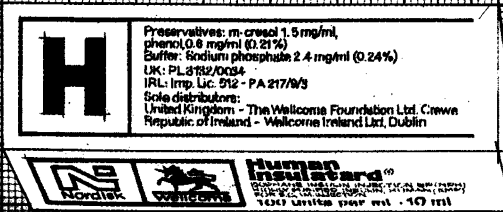
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