

# WILL HE BE WEARING CHILDREN'S CLOTHES WHEN HE'S A 'GROWN-UP'?

## Prescribing Information

**Presentation** A vial of sterile lyophilised powder of somatrem corresponding to 4IU 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.

## 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. **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.

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

**Price** NHS Price £28

**Further Information** Somatrem is the British Approved Name for methionyl human somatotropin.

**Product Licence Number** 0022/0060

**KabiVitrum Limited.** KabiVitrum House, Riverside Way, Uxbridge, Middx UB8 2YF.

**Product Authorisation Number** 187/28/1.

**Etire** KabiVitrum, Cahill May Roberts Ltd, P.O. Box 1090, Chapelizod, Dublin 20.



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	<b>Thema des Monats</b> Elementardiäten beim Morbus Crohn Molekularbiologische Hilfen zur Neuroblastom- diagnostik	<b>This Month's Topic</b> Elemental Diet in Crohn's Disease Molecular-Biological Aids in the Diagnosis of Neuroblastoma	665
H. M. A. Kirchmann V. Schuster, H. W. Kreth	Die Bedeutung von Elementardiäten in der Therapie des Morbus Crohn im Kindesalter Molekularbiologische Aspekte des Neuroblastoms	The Role of Elemental Diet in the Treatment of Crohn's Disease in Children Molecular-Biological Aspects of Neuroblastoma	666 672
	<b>Pädiatrie aktuell</b>	<b>Trends in Paediatrics</b>	677
	<b>Was hat das Kind?</b> Trainingsprogramm für die Weiterbildung zum Kinderarzt	<b>What's Wrong with the Child?</b> Program for Continuing Education of Paediatricians	678
	<b>Aus Klinik und Forschung Originalien</b>	<b>Clinic and Research Originals</b>	
R. Tangemann, B. McCarthy, E. Schmidt, M. Limbacher C. Severien, C. Mietens	Zur hohen Nachsterblichkeit der Säuglinge in NRW  Untersuchungen zum Einfluß von Stickoxid- und Schwebstaubgehalt der Luft auf die Häufigkeit von stationär behandelten Kindern mit stenosie- render Laryngotracheitis (Pseudokrapp)	On the High Infant Mortality Rate in North Rhine Westphalia  Studies on the Influence of Atmospheric Nitro- gene Dioxide, Nitrogen Monoxide and Small Par- ticle Dust on the Incidence of Stenosing Laryngo- tracheitis (Croup) in Children Hospitalized for it	679  686
R. Gonzalez V., W. H. Hei3s, W. Rauh	Stumpfes Bauchtrauma verursacht durch Kindes- mißhandlung	Abdominal Blunt Trauma Caused by Child Abuse	692
S. Wirth, G. Ehninger, W. Baumann E. Gladtko, U. Schausel-Zipf	Zur Behandlung konnataler Varizellen mit Aciclovir Reye-Syndrom	Treatment of Congenital Varicella with Acyclovir Reye's Syndrome	696 699
	<b>Der interessante Fall</b>	<b>Interesting Cases</b>	
I. Schulze, S. Mravak, B. Weber	Kala-Azar mit ausgeprägter Ferritinämie bei einem deutschen Schulkind	Kala-Azar and Marked Ferritinaemia in a German Schoolboy	705
R. Schulz, J. Vogt, W. Voss, F. Hanefeld	Mucopolidose Typ II (I-Cell Disease) mit unge- wöhnlich ausgeprägter Herzbeteiligung	Mucopolidosis Type II (I-Cell Disease) with Severe Cardiac Involvement	708
	<b>Wußten Sie schon?</b> <i>Aus der Praxis — für die Praxis</i> Die Behandlung eines asthmatischen Kindes wird effektiver, wenn die Mutter gut informiert ist, ihr Kind auskultiert und ein Tagebuch führt	<b>Do You Know?</b> <i>Practical Tips for Practitioners</i> More Effective Therapy of Asthma Bronchiale in Children by Winning Over the Mother to Join and Helping Her by Comprehensive Information About Disease and Treatment	712
M. Reinert	Auflösung und Kommentar des Trainings- programms für die Weiterbildung zum Kinderarzt	Solution and Commentary in the Program for Continuing Education of Paediatricians	685
	<b>Laudationes</b>	<b>Laudationes</b>	
C. Mietens	Josef Ströder 75 Jahre	Josef Ströder 75 Years	713
	<b>Aus Gesellschaften und Berufsverband</b>	<b>Society and Professional Organisations</b>	714
	<b>In memoriam</b>	<b>In memoriam</b>	
W. H. Hitzig	Wolf W. Zuelzer	Wolf W. Zuelzer	715
	<b>Tagesgeschichte, Personalia</b>	<b>News of the Day, Personal News</b>	716
	<b>Tagungskalender</b>	<b>Forthcoming Meetings</b>	716
	Zusammenfassungen der Vorträge der 17. Jahrestagung der Arbeitsgemeinschaft für Pädiatrische Nephrologie vom 12. — 14. März 1987 in Krefeld		717
	<b>Für die Dokumentation</b>	<b>Documentation</b>	A 48



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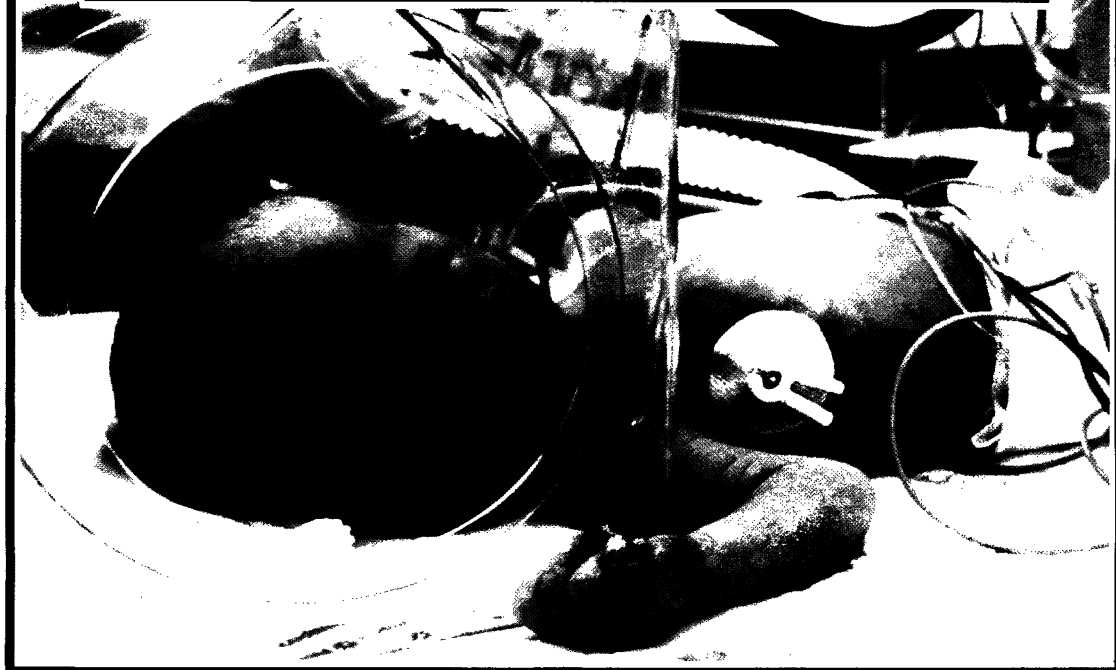
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#### Prescribing Information ▼

##### Indications

Virazid is indicated in the treatment of infants and children with severe respiratory syncytial virus bronchiolitis.

##### Dosage

Treatment is carried out using a small particle aerosol generator (SPAG) for 12-18 hours per day for at least 3 and no more than 7 days. The concentration of ribavirin in the reservoir is 20mg/ml in the SPAG unit and the average concentration for a 7 hour period is 0.19mg/l of air.

##### Presentation

Virazid is a sterile lyophilised powder of ribavirin to be reconstituted for aerosol administration. Each 100ml glass vial contains 6g of ribavirin and, when reconstituted to the correct volume of 300ml with Water for Injections BP, will

contain 20mg/ml ribavirin at a pH of approximately 5.5.

##### Contra-Indications

Ribavirin is contra-indicated in females who are or may become pregnant and it should be noted that ribavirin can be detected in human blood even four weeks after oral administration has ceased.

##### Precautions

In infants requiring assisted ventilation, Virazid should only be used when there is constant monitoring of both patients and equipment.

##### Side Effects

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assisted ventilation. These events included worsening of respiratory status, bacterial pneumonia and pneumothorax. The role of ribavirin aerosol in these events has not been determined.

Anaemia has been reported with oral and intravenous administration but no such incidents have been reported with aerosol administration. Reticulocytosis has been reported with aerosol use.

##### Warnings

Precipitation of the drug in respiratory equipment and consequent accumulation of fluid in the tubing has caused difficulties for patients requiring assisted ventilation.

In infants requiring assisted ventilation Virazid should only be used when there is constant monitoring of both patients and equipment.

Directions for use during assisted ventilation are given in the SPAG manual which should be read carefully before such administration.

Full prescribing information is available upon request.

▼ Special reporting to the CSM required.

Basic NHS Price: 1 x 6g vial £195.

Product Licence Number : 4657/0004

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