

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°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

N.H.S. Price £ 28

*For the first time
in the history of medicine
we can supply growth hormone
to every child
suffering from short stature
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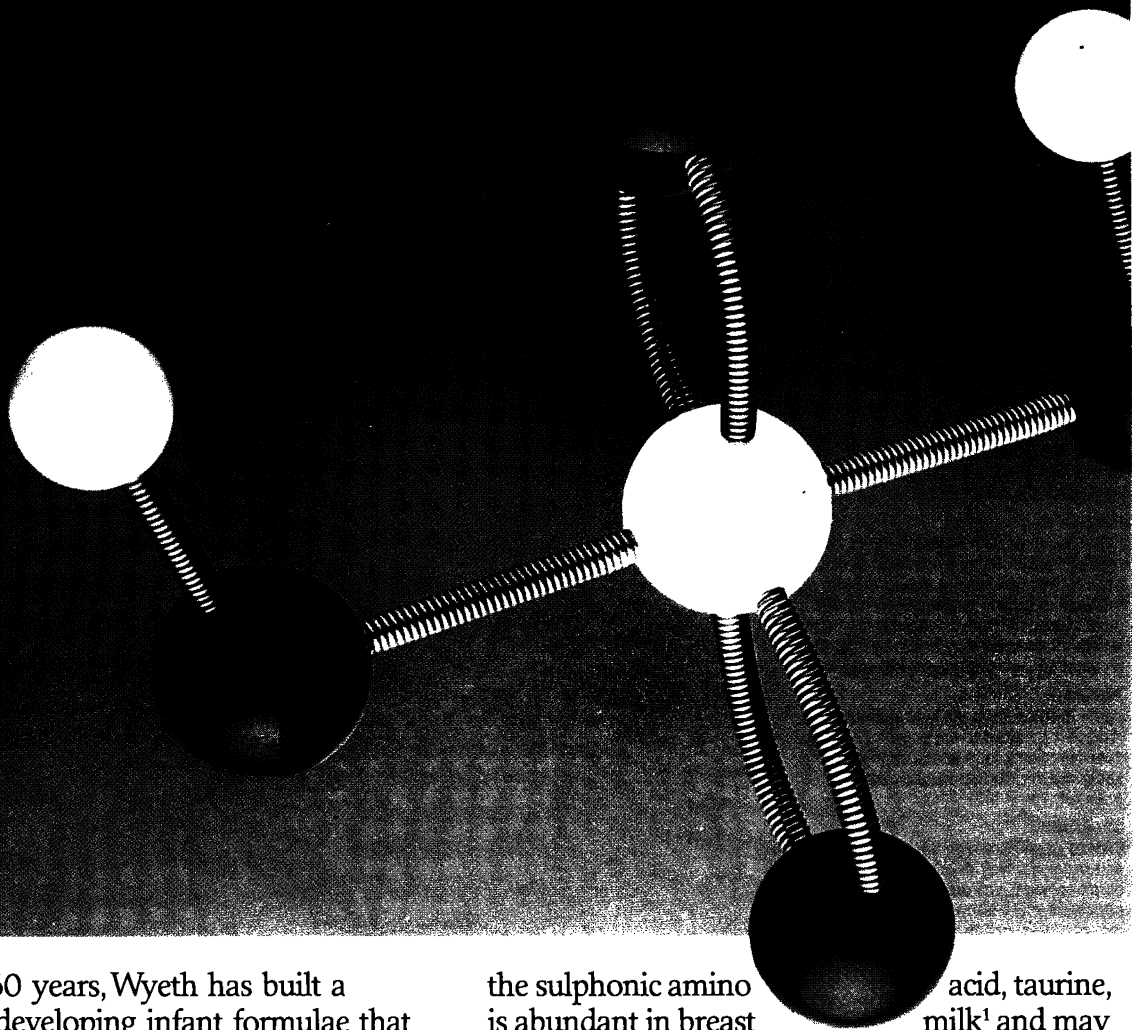
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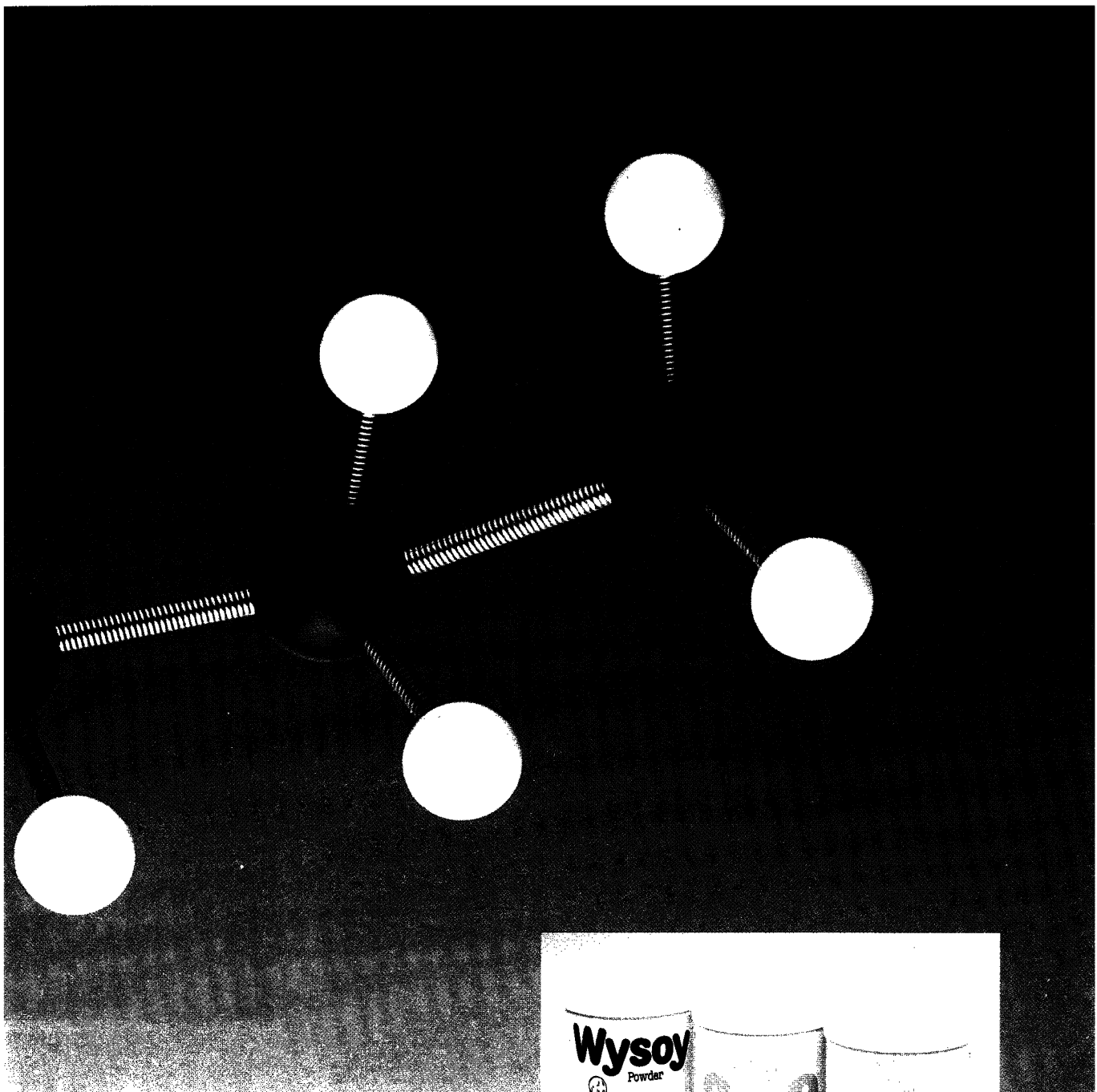
Nevertheless, work has continued towards both a fuller understanding of the differences between infant formulae and breast milk, and clarification of the possible metabolic significance these differences may have in the newborn.

Research pioneered by Wyeth shows that

the sulphonic amino acid, taurine, is abundant in breast milk¹ and may have a role in bile functions² and the developing central nervous system,³ retina,⁴ and myocardium.⁵

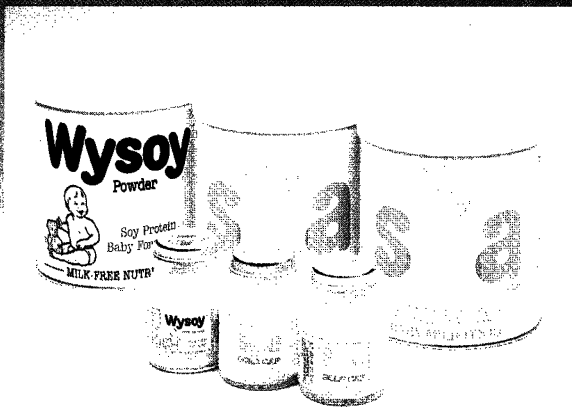
Breast milk should be the natural standard for all infant formulae. For this reason, taurine is now included in all Wyeth ready-to-feed and powder formulae to ensure continuity of good nutrition for bottle-fed babies throughout infancy.

Wyeth infant formulae with taurine – now even



Breast milk is best for babies. Infant formula is intended to replace or supplement breast milk when breast feeding is not possible or is insufficient, or when mothers elect not to breast feed. Good maternal nutrition is important for the preparation and maintenance of breast feeding. Extensive or prolonged use of partial bottle feeding, before breast feeding has been well established, could make breast feeding difficult to maintain. A decision not to breast feed could be difficult to reverse. Professional advice should be followed on all matters of infant feeding. Infant formula should always be prepared and used as directed. Unnecessary or improper use of infant formula could present a health hazard. Social and financial implications should be considered when selecting the method of infant feeding.

References: 1. Rassin D.K., Sturman J.A., Gauli G.E. (1978). Taurine and other free amino acids in milk of man and other mammals. *Early Human Development* 2/1. 1. 2. Jaavenpää A.L., Rasin D.K., Kuitunen P., Gauli G.E., Raihä N.C.R. (1983). Feeding the low birthweight infant: III Diet influences bile metabolism. *Paediatrics* 72, 677. 3. Sturman J.A., Gauli G.E. (1976). Taurine in the brain and liver of the developing human and rhesus monkey. In: Huxtable R., Barbeau A. (eds). *Taurine*. Raven Press, New York, pp 73-84. 4. Sturman J.A., Wen G.Y., Wisniewski H.M., Neuringer M.D. (1984). Retinal degeneration in primates raised on synthetic infant formula. *Int. J. Dev. Neurosci.* 2, 121. 5. Huxtable R.J., Sebring L.A. (1983). Cardiovascular actions of taurine. In: Kuriyama K., Huxtable R.J., Iwata H. (eds). *Sulfur Amino Acids: Biochemical and Clinical Aspects*, Alan R. Liss, New York, pp 5-37.



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Further information, including a review of the role of taurine is contained in a booklet "Taurine in Infant Nutrition" available on request from Wyeth Nutrition.

closer to breast milk.

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H. J. Heinz Company Limited generously endows Fellowships in Paediatrics which are administered by the British Paediatric Association.

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A To enable paediatricians from any part of the Commonwealth overseas to spend up to twelve weeks in the United Kingdom, meeting British Paediatricians and seeing something of their work. Preference will be given to those recently established in an academic career who can arrange their visit to allow attendance at the Annual Meeting of the British Paediatric Association in April 1988

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Applications for C Fellowships can be accepted by 31st January 1987 or 31st July 1987

The conditions for the Fellowships and applications forms may be obtained from the British Paediatric Association, 5 St Andrew's Place, Regent's Park, London NW1 4LB

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.

Full Prescribing Information Available From: Eli Lilly and Company Limited, Kingsclere Road, Basingstoke, Hampshire RG21 2XA. Telephone: Basingstoke (0256) 473241.

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Hu 141 March 1986





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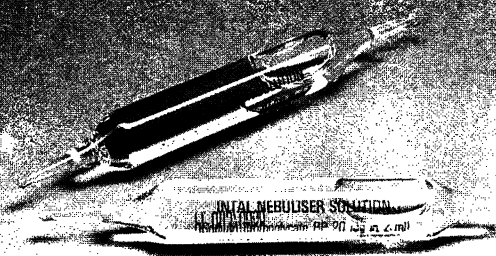
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Uses The active treatment of allergic asthma. Also prevents the production of asthma symptoms such as coughing, wheezing and chest tightness. **Dosage and Administration** See the full prescribing information for details of the recommended regimen. This is available on request from the manufacturer. **Contra-indications** Administration should be avoided in children with known hypersensitivity to any of the ingredients.

Contra-indications, Warnings etc. There are no specific contra-indications. **Side effects** Local allergic reactions may occur. **Basic NHS Cost and Product Licence Number** 04/03/028. **Registered trade marks**

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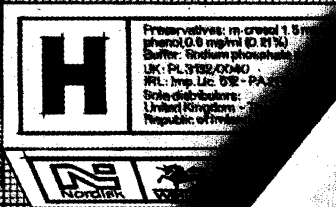
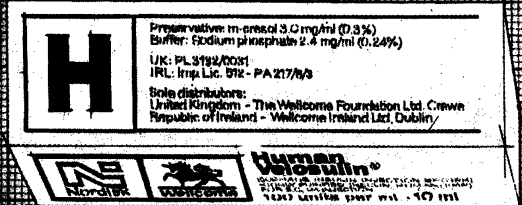
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für Kinderheilkunde

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Vorträge der 81. Tagung der Deutschen Gesellschaft für Kinderheilkunde vom 1. bis 4. September 1985 in Frankfurt/Main

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