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.

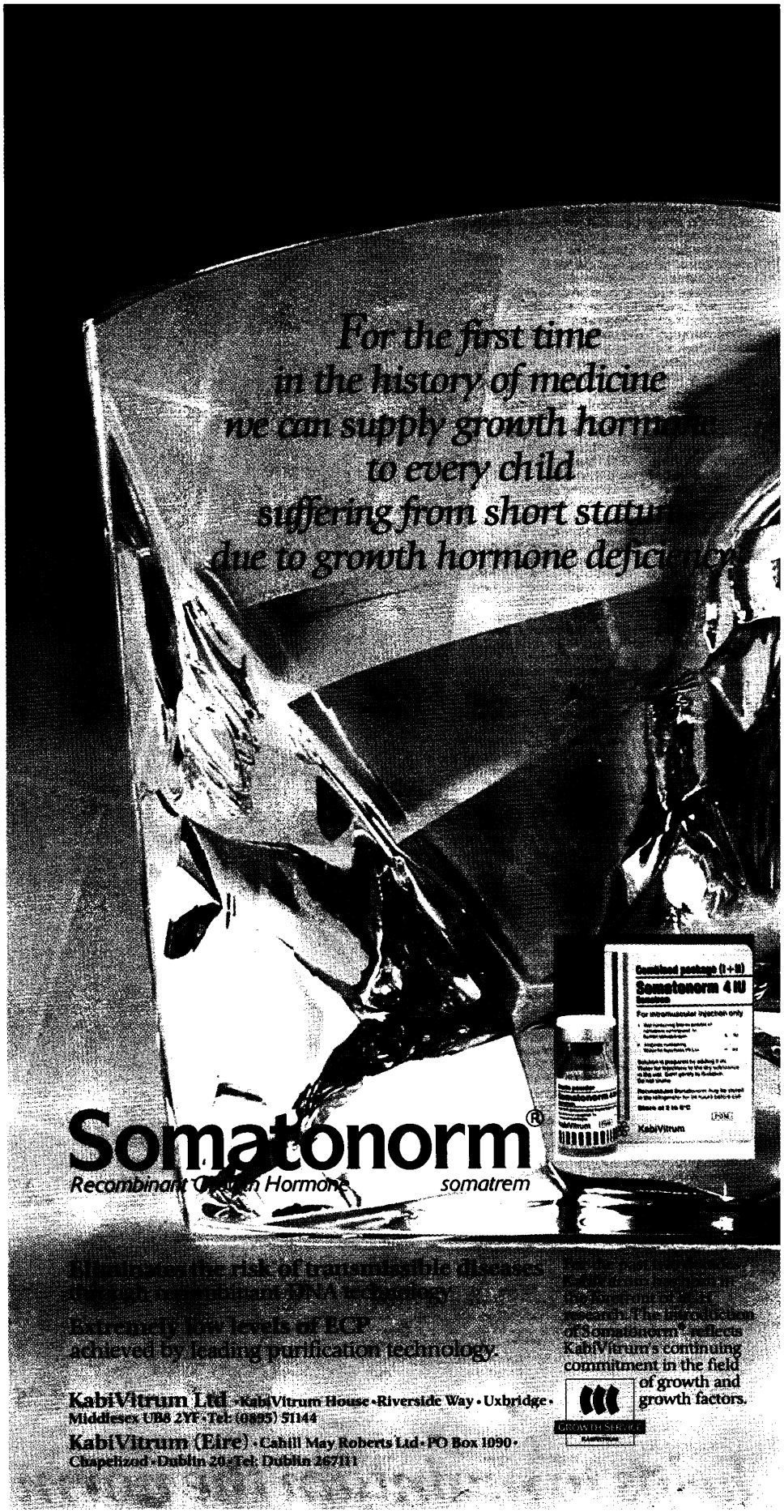
LEGAL CATEGORY
POM.

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



Epilim®
sodium valproate

In a wide range of epilepsies

Presentation 1. Epilim 200 Enteric Coated. A lilac-coloured enteric coated tablet containing 200mg sodium valproate. 2. Epilim 500 Enteric Coated. A lilac-coloured enteric coated tablet containing 500mg sodium valproate. 3. Epilim 100mg crushable tablets. A white scored tablet containing 100mg sodium valproate. 4. Epilim Syrup. A red, cherry-flavoured syrup containing 200mg sodium valproate per 5ml. 5. Epilim Liquid. A red, cherry-flavoured, sugar-free liquid containing 200mg sodium valproate per 5ml. **Indications** In the treatment of generalised, partial or other epilepsies. In women of child-bearing age Epilim should be used only in severe cases or in those resistant to other treatment. **Dosage and Administration** To be taken with or after food. Epilim may be given twice daily. Enteric coated tablets should be swallowed whole. **Monotherapy** *Adults:* Start at 600mg/daily increasing by 200mg at 3 day intervals until control is achieved. (Maximum dose 2,500mg per day). *Children over 20kg:* Initially 400mg/day with spaced increases until control is achieved. (Usually within the range 20-30mg/kg body weight per day). *Children under 20kg:* 20mg/kg of body weight per day: in severe cases may be increased up to 40mg/kg day. Increases above this only if plasma valproic acid levels, clinical chemistry and haematological parameters can be monitored. **Combined Therapy** It may be necessary to raise the dose when used with anticonvulsants which induce liver enzyme activity. Dosage of barbiturates should be reduced if sedation is observed. Optimum dosage is mainly determined by seizure control and routine measurement of plasma levels is unnecessary. **Contra-indications, Warnings; Contra-indication:** Active liver disease. **Side effects:** Liver dysfunction including hepatic failure resulting in fatalities has occurred in patients whose treatment included valproic acid or sodium valproate. The incidents mainly occurred during the first 6 months of therapy. Clinical symptoms are more helpful than laboratory investigations in the early stages of hepatic failure. The onset of an acute illness, especially within the first 6 months, which may include symptoms of vomiting, lethargy or weakness, drowsiness, anorexia, jaundice or loss of seizure control is an indication for immediate withdrawal of the drug. Evidence to date does not establish which investigation could predict this possible adverse effect: measurement of liver function should be performed in the first 6 months of therapy in those who seem most at risk. Hyperammonaemia without hepatic damage can occur, it is usually transient, but may occasionally present clinically. If so Epilim should be discontinued. Valproic acid inhibits platelet aggregation. Thrombocytopenia has been reported. Spontaneous bruising or bleeding is an indication for withdrawal of medication. Pancreatitis, tremor, weight gain, transient hair loss, increased alertness, aggressiveness, hyperactivity, amenorrhoea, stupor and oedema have been reported. **Drug Interactions** Epilim may potentiate monoamine oxidase inhibitors and other anti-depressants. Loss of efficacy of oral contraceptive agents does not appear to be a problem. **Women of Childbearing Age** Valproic acid and sodium valproate, like certain other anti-convulsants, have been shown to be teratogenic in animals. In women of childbearing age the benefits of these compounds should be weighed against the possible hazard suggested by these findings and their pregnancies should be carefully monitored. **Product Licence Numbers** Epilim 200 Enteric Coated 0623/0006. Epilim 500 Enteric Coated 0623/0005. Epilim 100mg crushable tablets 0623/0015. Epilim Syrup 0623/0004. Epilim Liquid 0623/0016. **NHS Cost** Epilim 200 Enteric Coated 100 tablets, £6.59. Epilim 500 Enteric Coated 100 tablets, £16.45. Epilim 100mg crushable tablets 100 tablets, £3.99. Epilim Syrup 200ml, £4.03. Epilim Liquid 200ml, £4.03. Further information is available from: Labaz: Sanofi UK Ltd., Floats Rd., Wythenshawe, Manchester M23 9NF. Tel: 061-945 4161.

Labaz

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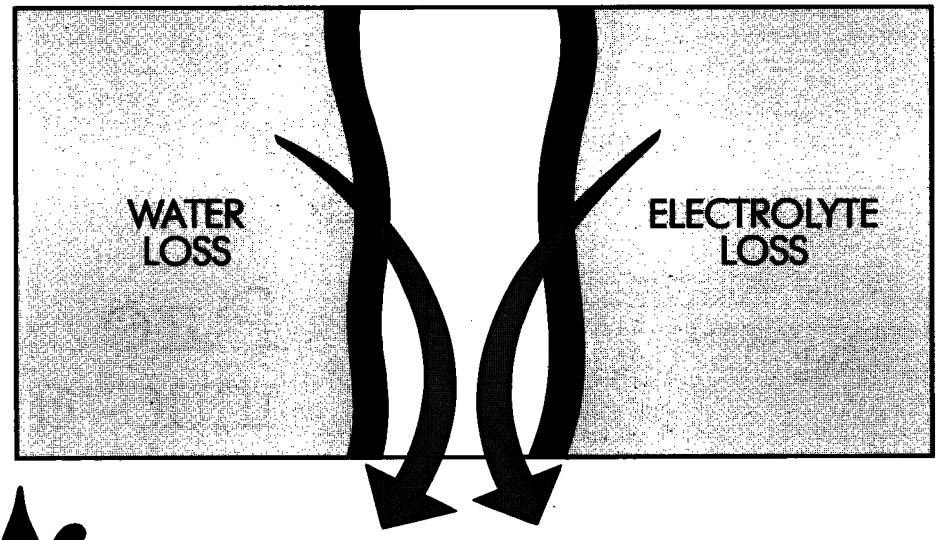
sodium valproate

helps to maintain the normality of life

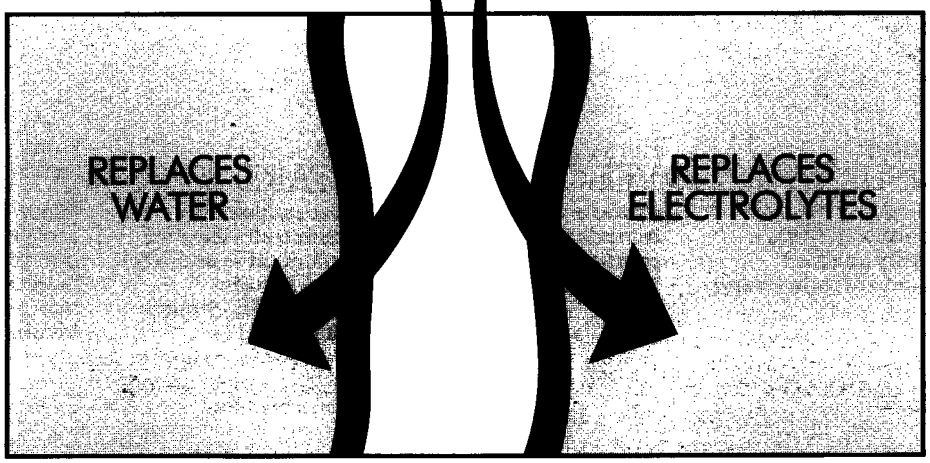
In childhood diarrhoea



Rehidrat®

balanced sugar/electrolyte powder

**active ingredients: Sodium chloride
Potassium chloride
Sodium bicarbonate**



restores the balance

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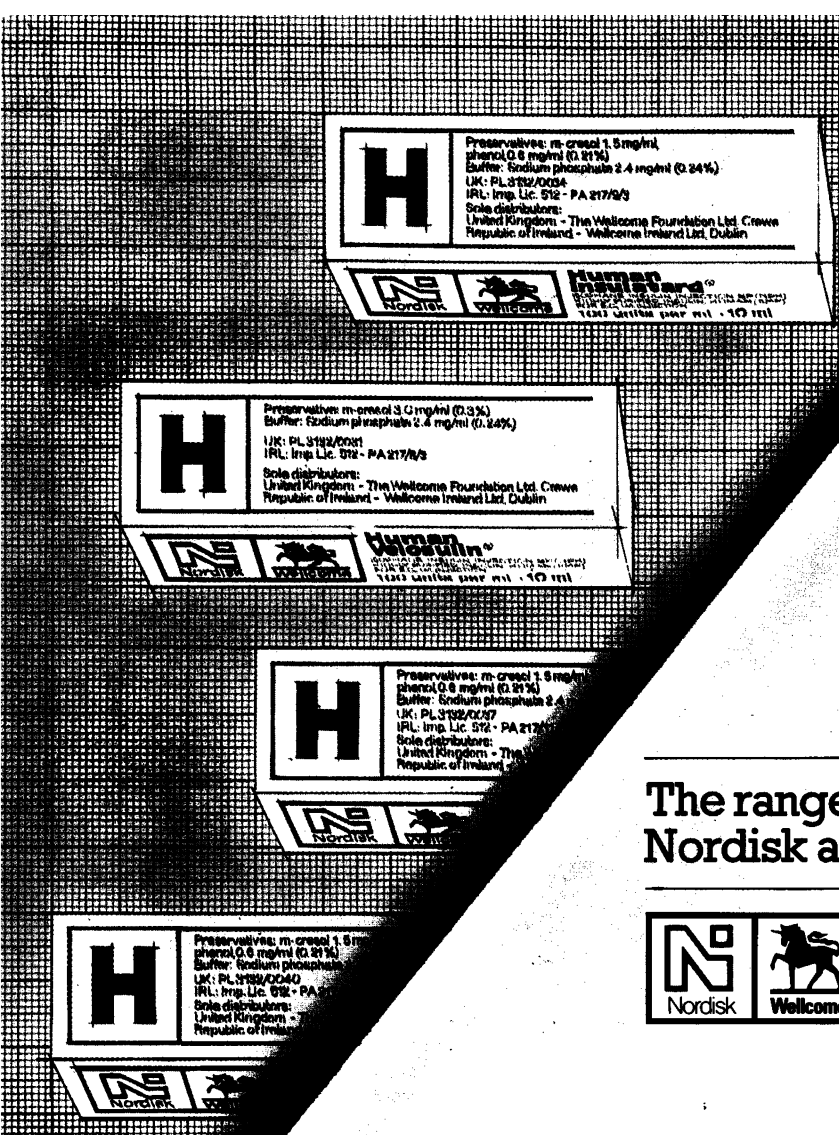
SEARLE

Searle Pharmaceuticals, Division of G. D. Searle & Co. Ltd. P.O. Box 53, Lane End Road, High Wycombe, Buckinghamshire HP12 4HL. Telephone: High Wycombe (0494) 21124. Searle and Rehidrat are registered trademarks.



Pure innovation revealed

The range of human insulins from Nordisk and Wellcome

Nordisk Wellcome

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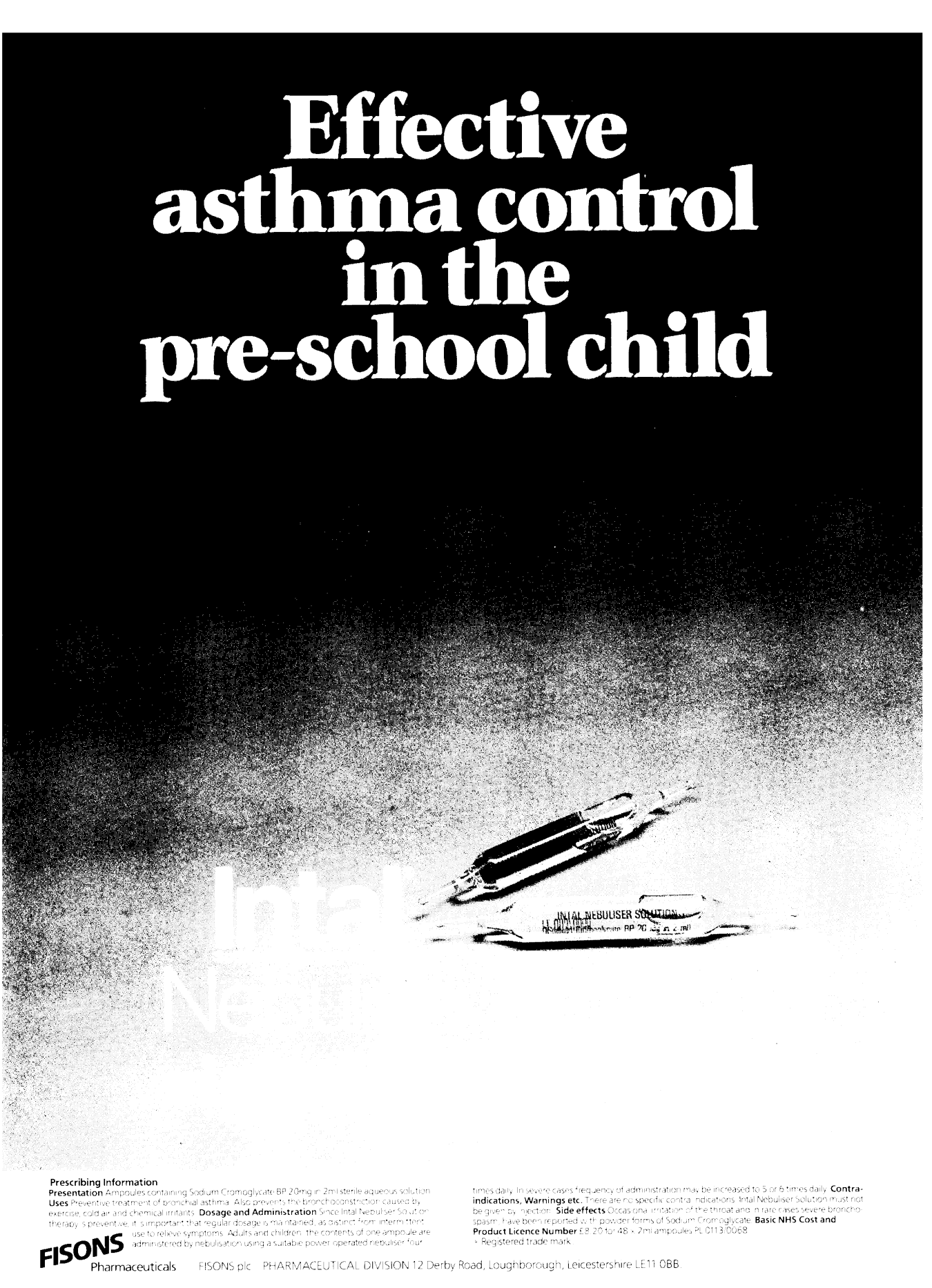
Highview House
Tattenham Crescent
Epsom KT18 5QJ
Tel. No: Burgh Heath (07373) 60621

The Wellcome Foundation Ltd.
Crewe Hall
Crewe
Cheshire CW1 1UB
Tel. No: Crewe (0270) 583151

- Human **INSULATARD** **(Isophane Insulin Injection [NPH], highly purified human insulin [emp])**
- Human **VELOSULIN** **(Neutral Insulin Injection, highly purified human insulin [emp])**
- Human **MIXTARD 30/70** **(Neutral suspension comprising 30% Neutral Insulin Injection and 70% Isophane Insulin Injection [NPH] – human insulin [emp])**
- Human **INITARD 50/50** **(Neutral suspension comprising 50% Neutral Insulin Injection and 50% Isophane Insulin Injection [NPH] – human insulin [emp])**

COMPOSITION HUMAN INITARD 50/50 (Neutral Suspension comprising 50% Neutral Insulin Injection and 50% Isophane Insulin Injection [NPH]). HUMAN VELOSULIN, HUMAN INSULATARD, HUMAN MIXTARD 30/70 and HUMAN INITARD 50/50 are manufactured from highly purified human insulin (emp). **PRESENTATION** HUMAN VELOSULIN, HUMAN INSULATARD, HUMAN MIXTARD 30/70 and HUMAN INITARD 50/50 are available in 10ml vials containing 100iu/ml. To provide sensory identification the metal sealing rings of the vial have tactile marks and the vials are also fitted with colour coded tamper-proof caps. **USES** Treatment of Insulin Dependent Diabetics. Human Velosulin is particularly suitable in the treatment of diabetic coma and precoma. **DOSAGE AND ADMINISTRATION** Dosage to be determined by the physician, according to the needs of the patient. Avoid accidental intra-vascular injection. **CONTRA-INDICATIONS AND WARNINGS** Insulin is contra-indicated in hypoglycaemia. In the event of overdosage, glucose should be given either orally or intravenously. Glucagon may also be administered. Human Insulatard, Human Mixtard 30/70, Human Initard 50/50, should not be given intravenously or intravascularly. Treatment with cortico-steroids, oral contraceptives or thyroid hormones may lead to an increase in dosage requirements. Beta-blockers may affect insulin requirements and mask hypoglycaemia. U100 insulin must only be used in U100 syringes. **PHARMACEUTICAL PRECAUTION** Store at 2 to 8 degrees C, protected from sunlight. Do not freeze. **LEGAL CATEGORY** P **BASIC NHS PRICE** HUMAN VELOSULIN, HUMAN INSULATARD, HUMAN MIXTARD 30/70 and HUMAN INITARD 50/50: 10 ml vial £6.95. **PRODUCT LICENCE NUMBERS** Human Velosulin 3132/0031 and 0003/0211. Human Insulatard 3132/0034 and 0003/0212. Human Mixtard 30/70 3132/0037 and 0003/0213. Human Initard 50/50 3132/0040 and 0003/0214.

Effective asthma control in the pre-school child



Prescribing Information
Presentation Ampoules containing Sodium Cromoglycate BP 20mg in 2ml sterile aqueous solution. **Uses** Preventive treatment of bronchial asthma. Also prevents the bronchoconstriction caused by exercise, cold air and chemical irritants. **Dosage and Administration** Since Intal Nebuliser Solution therapy is preventive, it is important that regular dosage is maintained, as distinct from intermittent use to relieve symptoms. Adults and children: the contents of one ampoule are administered by nebulisation using a suitable power operated nebuliser four times daily. In severe cases frequency of administration may be increased to 5 or 6 times daily. **Contra-indications, Warnings etc.** There are no specific contra-indications. Intal Nebuliser Solution must not be given by injection. **Side effects** Occasional irritation of the throat and, in rare cases severe bronchio-spasm. Have been reported with powder forms of Sodium Cromoglycate. **Basic NHS Cost and Product Licence Number** £8.20 for 48 × 2ml ampoules PL 0113/0068.
× Registered trade mark.

FISONS Pharmaceuticals FISONS plc PHARMACEUTICAL DIVISION 12 Derby Road, Loughborough, Leicestershire LE11 0BB.

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Indications Epilepsy (generalised tonic-clonic and partial seizures).
Dosage in epilepsy Use a gradually increasing dosage scheme, adjusting to patient's needs. Adults: 100-200mg once or twice daily, increasing slowly up to 800-1,200mg daily; in some cases 1,600mg daily may be necessary. Children: up to 1 year old, 100-200mg daily, aged 1-5 years, 200-400mg daily; aged 5-10 years, 400-600mg daily; aged 10-15 years, 600-1,000mg daily. It may be helpful to monitor plasma drug levels: optimum therapeutic range is 3-10μg/ml (13-42μmols/l).
Side-effects Dizziness and diplopia (usually dose-dependent), less frequently dry mouth, nausea and vomiting. Generalised erythematous rash, disappearing on cessation of therapy. Isolated reports of oedema, hyponatraemia, exfoliative dermatitis, leucopenia, thrombocytopenia, agranulocytosis, aplastic anaemia, cholestatic jaundice and acute renal failure. Blood count should be checked in early stages of treatment.
Precautions Caution in patients taking oral anticoagulants or requiring oral contraception.
In pregnancy, potential benefits of Tegretol must be weighed against potential hazards. Do not administer with, or within two weeks of cessation of, MAOI therapy.
In rats treated with carbamazepine for two years, incidence of liver tumours increased (no evidence of significant bearing on the therapeutic use of the drug). Serum folic acid levels should be observed during anticonvulsant therapy.
Contra-indications Previous drug sensitivity to Tegretol. Do not administer to patients with atrioventricular conduction abnormalities unless paced.
Packs Tablets of 100mg (PL0001/5027) basic NHS price £2.90 per 100, £13.95 per 500; tablets of 200mg (PL0001/5028 £5.38 per 100, £25.93 per 500; tablets of 400mg (PL0001/0088) £10.58 per 100, syrup 100mg/5ml (PL0001/0050) £5.17 per 300ml bottle.
* denotes registered trademark. Full prescribing information is available on request from Geigy Pharmaceuticals, Horsham, West Sussex.

Geigy

Tegretol*
carbamazepine BP

for the effective control of epilepsy

TG1