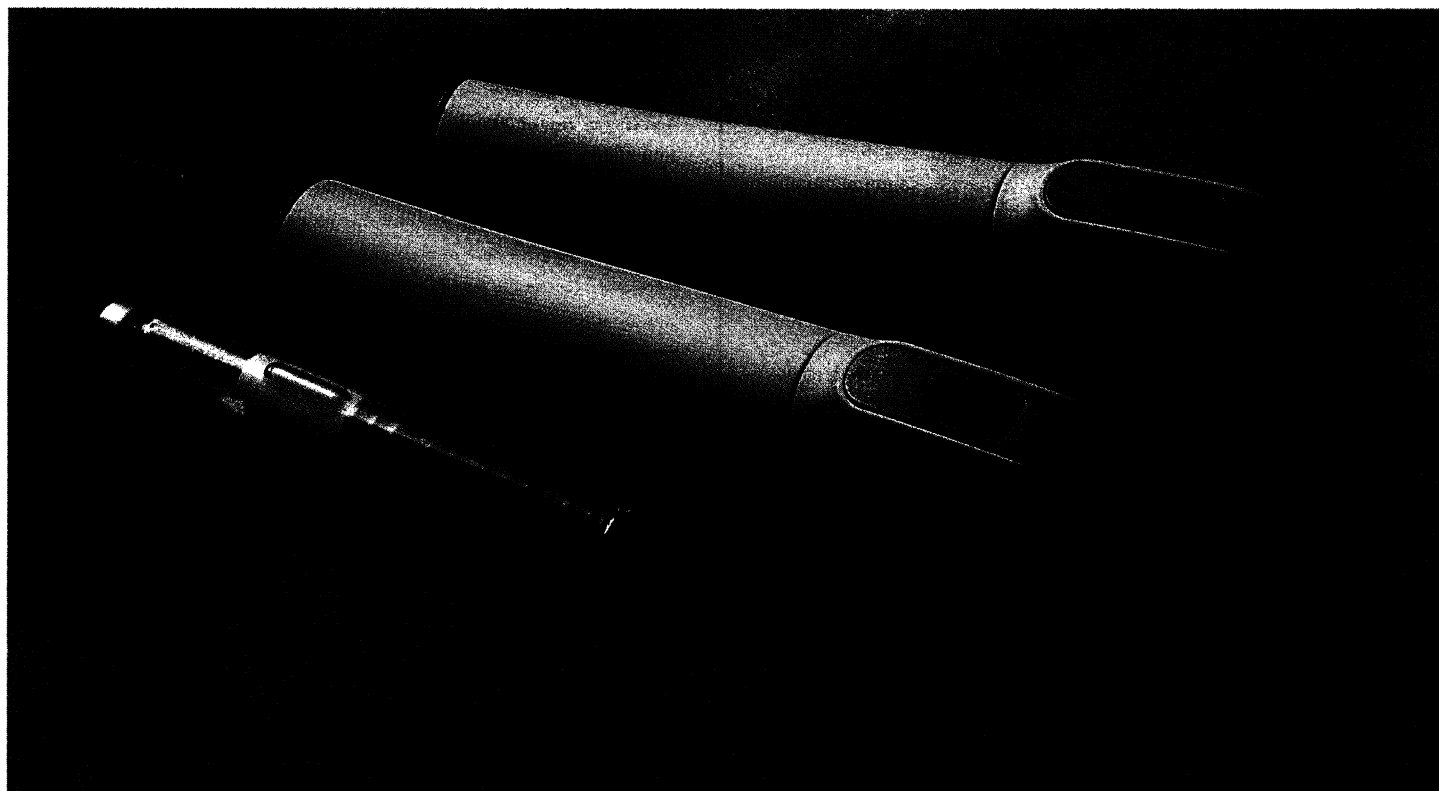


# Genotropin<sup>®</sup> Pen

somatropin (rbe)

## Simplifies GH therapy for the patient and the clinic



### GENOTROPIN<sup>®</sup> (somatropin, rbe)

#### Abbreviated Prescribing Information

Genotropin 36 IU, Genotropin 16 IU, Genotropin 4 IU KabiVial Multidose, Genotropin 2,3 and 4 IU KabiQuick

#### Presentation

**Genotropin 36 IU.** Two compartment cartridge for use in either the Genotropin Pen 36 or KabiMixer devices. One compartment contains 36 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections.

**Genotropin 16 IU.** Two compartment cartridge for use in either the Genotropin Pen 16 or KabiMixer devices. One compartment contains 16 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections.

**Genotropin 4 IU KabiVial Multidose.** Two compartment cartridge in a reconstitution device. The first compartment contains 4 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections.

**Genotropin 2, 3 and 4 IU KabiQuick.** Two compartment cartridge in a single dose syringe for reconstitution and injection. The first compartment contains 2, 3 or 4 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.5ml, 0.75ml or 1ml Water for Injections respectively

#### Uses

Treatment of growth disturbance due to insufficient secretion of growth hormone or associated with gonadal dysgenesis (Turner Syndrome). Treatment of growth disturbance in prepubertal children with chronic renal insufficiency (CRI).

#### Dosage and Administration.

**Route of Administration:** Subcutaneous injection.

Dosage is individual.

**Insufficient secretion of growth hormone:** generally a dose of 0.5-0.7 IU/kg body weight per week (14 - 20 IU/m<sup>2</sup> body surface area per week) is recommended. Higher doses have been used.

**Gonadal dysgenesis (Turner Syndrome):** a dose of 1 IU/kg body weight per week (28 IU/ m<sup>2</sup> body surface area per week) is recommended.

**CRI:** a dose of 30 IU/ m<sup>2</sup> body surface area per week (approximately 1 IU/kg body weight per week) is

recommended. Higher doses may be needed if growth velocity is too low. Dose correction may be required after six months treatment. The weekly dose should be divided into 6 - 7 subcutaneous injections. The injection site should be varied to prevent lipoatrophy.

#### Preparation of solution

Somatropin (rbe) is reconstituted using the KabiMixer, KabiVial, KabiQuick or Genotropin Pen devices. Instructions on how to effect reconstitution are supplied separately at the specialist growth clinic, as are the Genotropin Pen and KabiMixer devices, and necessary needles.

#### Contra-indications, Warnings etc.

Genotropin should not be used when there is any evidence of tumour activity. Intracranial lesions must be inactive and any antitumour therapy completed prior to starting therapy. Genotropin should not be used for growth promotion in patients with closed epiphyses.

**Precautions:** Therapy with Genotropin should be initiated by suitably qualified physicians. In diabetes mellitus, insulin dosage may need adjustment. Thyroid function may be affected and should be monitored periodically. In patients with endocrine disorders, slipped epiphyses of the hip may occur. Some rare cases of benign intracranial hypertension have been reported. In chronic renal insufficiency, renal function should have decreased to below 50 per cent of normal and disturbed growth followed for a year preceding institution of therapy. Conservative treatment for renal insufficiency should have been established and should be maintained during treatment. Treatment should be discontinued after renal transplantation.

**Pregnancy and Lactation:** Clinical experience of use in pregnancy is limited. Treatment should be interrupted if pregnancy occurs. **Overdosage:** Acute overdosage is unlikely, though may lead initially to hypoglycaemia and subsequently to hyperglycaemia. Long-term overdosage could result in symptoms consistent with the known effects of growth hormone excess.

**Side Effects:** Common effects are related to transient local skin reactions.

#### Pharmaceutical Precautions

Store at 2-8° C. Protect from light. Once reconstituted Genotropin should be stored in the refrigerator and protected from light. Genotropin 36 IU, Genotropin 16 IU

and Genotropin 4 IU KabiVial Multidose in use may be stored for up to 14 days under these conditions. Once reconstituted Genotropin 2,3 and 4 IU KabiQuick should be used immediately, or within 24 hours if kept in the refrigerator.

#### Legal Category

POM

#### Package Quantities

**Genotropin 36 IU.** Pack containing one cartridge for use in the Genotropin Pen 36/KabiMixer devices.

**Genotropin 16 IU.** Pack containing one cartridge for use in the Genotropin Pen 16/KabiMixer devices.

**Genotropin 4 IU KabiVial Multidose.** Two compartment cartridge in a reconstitution device. Pack containing one Genotropin 4 IU KabiVial Multidose.

**Genotropin 2, 3 and 4 IU KabiQuick.** Two compartment cartridge in a reconstitution and injection device.

Pack containing ten Genotropin 2 IU KabiQuicks

Pack containing ten Genotropin 3 IU KabiQuicks

Pack containing ten Genotropin 4 IU KabiQuicks

#### Product Licence Numbers and Basic NHS Prices:

36 IU	0022/0098	1 x 36 IU	£274.50
16 IU	0022/0085	1 x 16 IU	£122.00
4 IU KabiVial Multidose	0022/0088	1 x 4 IU	£30.50
2 IU KabiQuick	0022/0089	10 x 2 IU	£160.00
3 IU KabiQuick	0022/0090	10 x 3 IU	£240.00
4 IU KabiQuick	0022/0091	10 x 4 IU	£320.00

#### Product Licence Holder

Pharmacia Ltd, Davy Avenue, Milton Keynes, MK5 8PH.

Further information is available on request from the Product Licence holder. Genotropin, KabiMixer, KabiVial and KabiQuick are registered trademarks. Date of preparation: November 1995.

  
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### Epilim Oral Prescribing Information

**Presentation** Epilim 200 Enteric Coated and Epilim 500 Enteric Coated: Enteric coated tablets containing 200mg, and 500mg Sodium Valproate Ph.Eur. respectively. Epilim Crushable Tablets containing 100mg Sodium Valproate Ph.Eur. Epilim Syrup and Epilim Liquid (sugar free) both containing 200mg Sodium Valproate Ph.Eur. per 5ml. Epilim Chrono 200, Epilim Chrono 300, and Epilim Chrono 500: Controlled release tablets containing a mixture of Sodium Valproate Ph.Eur. and Valproic Acid Fr.P. equivalent to 200mg, 300mg, and 500mg Sodium Valproate respectively.

**Indications** Oral formulations of Epilim are indicated for all types of epilepsy. In women of child bearing age Epilim should be used only in severe cases or in those resistant to other treatment. **Dosage and administration** *Adults*; the dose should be titrated at three day intervals until seizure control is achieved. Initially 600mg a day increasing in steps of 200mg to a maximum dose of 2500mg per day. *Children over 20kg*; initially 400mg a day increasing in steps to a maximum dose of 35mg/kg/day. *Children under 20kg*; initially 20mg/kg/day - the dose may be increased in steps to a maximum of 40mg/kg/day provided that plasma levels are monitored. Epilim Chrono may be given once or twice daily. All other formulations should be given twice daily. **Combination therapy**; levels of Epilim and co-administered anticonvulsants may be affected and optimum dosage is determined by seizure control.

**Contraindications, Warnings, etc.** **Contraindications** Active liver disease, family history of severe liver disease, hypersensitivity to valproate. **Side effects** Impaired hepatic function, particularly in children, occasionally leading to hepatic failure - treatment should be withdrawn in patients who suddenly develop symptoms compatible with hepatic disease such as nausea, anorexia, jaundice or malaise. Hyperammonaemia with or without hepatic dysfunction. Blood dyscrasia - impaired platelet function, thrombocytopenia, occasional leucopenia and red cell hypoplasia. Occasionally increased appetite, weight gain, transient hair loss, behavioural disturbances, alterations to the menstrual cycle and pancreatitis. Symptoms of intoxication include ataxia, tremor, and stupor. **Drug interactions** Epilim has significant interactions with phenytoin, lamotrigine and other anticonvulsants. Epilim may potentiate the effects of neuroleptics, MAOIs and other antidepressants, anticoagulants and salicylates. Cimetidine may inhibit the metabolism of Epilim. Epilim has no effect on the efficacy of oral contraceptives. **Pregnancy** An increased incidence of congenital abnormalities has been demonstrated in offspring born to mothers with epilepsy both untreated and treated, including those treated with sodium valproate. Neural tube defects have been reported in about 1% of offspring of women who have received valproate during the first trimester of pregnancy. Pregnancies should be screened for neural tube defects by estimation of alpha-fetoprotein and ultrasound. Folate supplementation has been shown to reduce the incidence of neural tube defects in the offspring of high risk women. **Legal category** P.O.M. **Further information** Epilim is hygroscopic - tablets should not be removed from their foil until they are used. Epilim Chrono is recommended in cases where plasma valproate levels are being measured on account of its pharmacokinetics. The effective therapeutic range for valproate is 40-100mg/l (278-694 micromol/l). **Product Licence Numbers** Epilim 200 Enteric Coated 11723/0018, Epilim 500 Enteric Coated 11723/0020, Epilim 100mg Crushable Tablets 11723/0017, Epilim Syrup 11723/0025, Epilim Liquid 11723/0024, Epilim Chrono 200 11723/0078, Epilim Chrono 300 11723/0021, Epilim Chrono 500 11723/0079. **NHS Cost** Epilim 200 Enteric Coated 100 tablets £6.42, Epilim 500 Enteric Coated 100 tablets £16.04, Epilim 100mg Crushable Tablets 100 tablets £3.89, Epilim Syrup 300ml £5.89, Epilim Liquid 300ml £5.89, Epilim Chrono 200 100 tablets £7.70, Epilim Chrono 300 100 tablets £11.55, Epilim Chrono 500 100 tablets £19.25. **Address:** Sanofi Winthrop Ltd., One Onslow Street, Guildford, Surrey GU1 4YS. **Telephone:** (01483) 505515 **Fax:** (01483) 35432. Epilim, Epilim Chrono and the Chrono device are registered trade marks. **Date of preparation** August 1995.

### References:

1. Chadwick D., *J. Neurol. Neurosurg. Psychiatry* 1994; 57: 264-277.
2. Gilham R.A., *Epilepsy Res.*, 1990; 7: 219-225.

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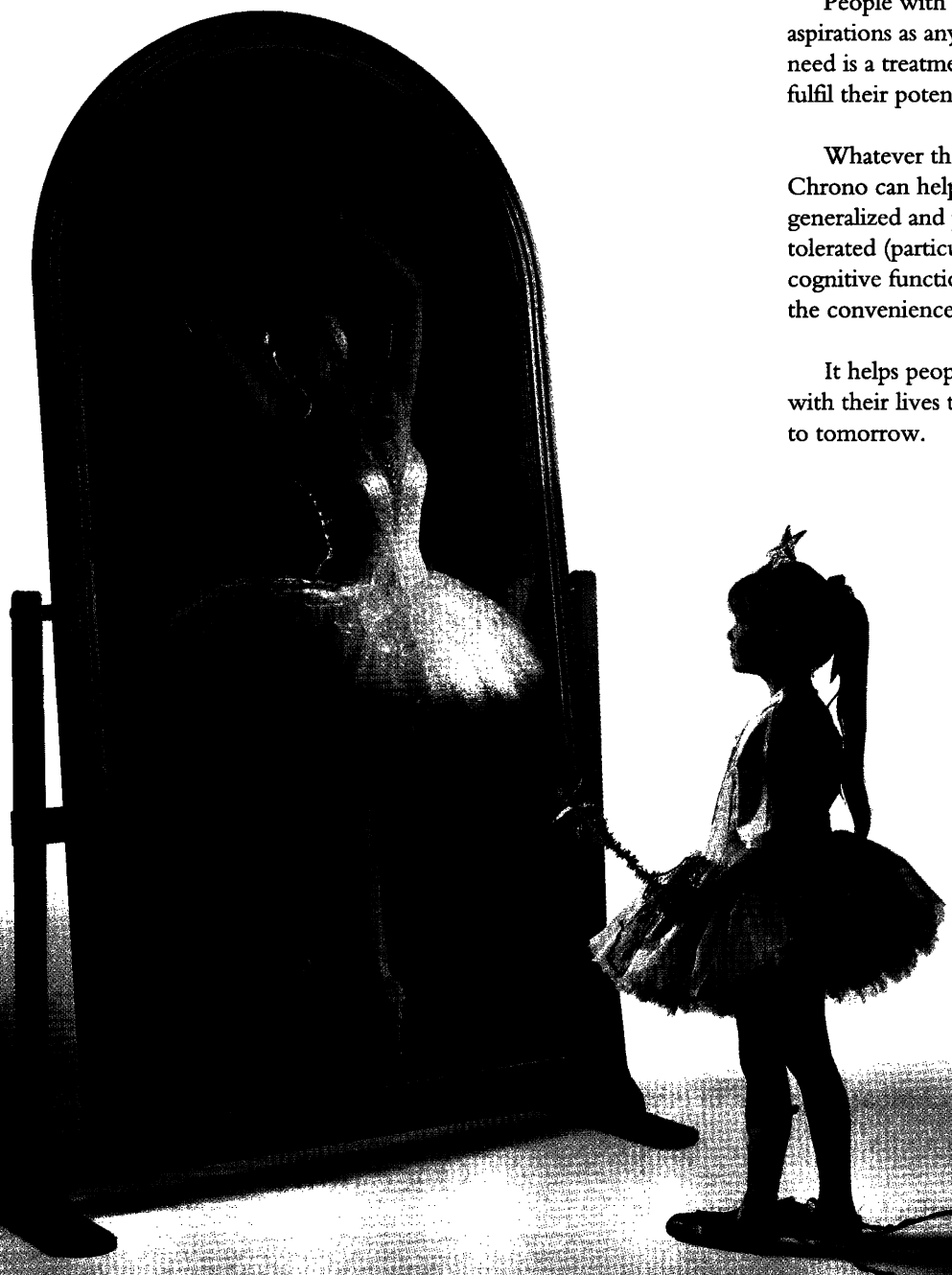
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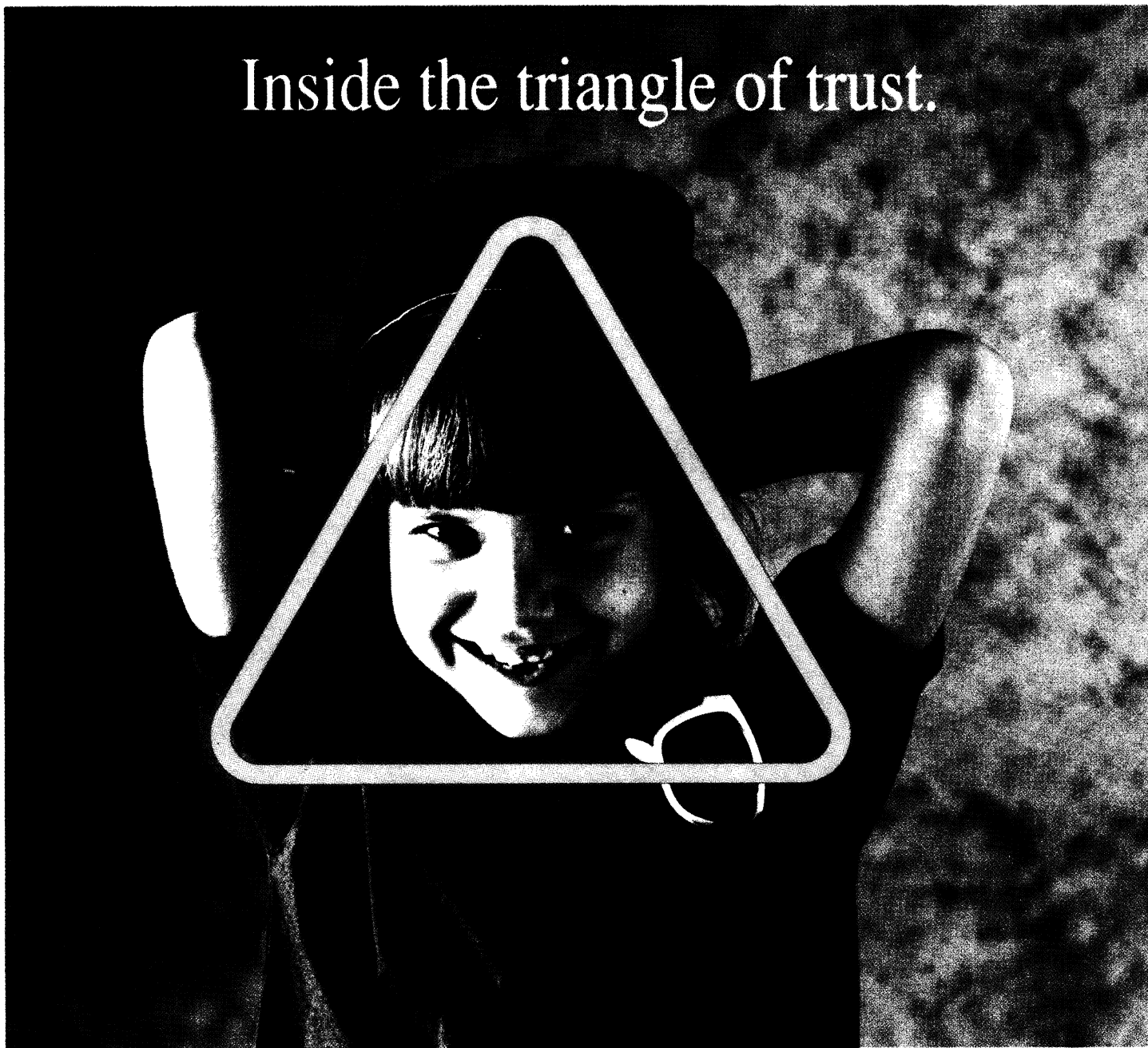
It helps people with epilepsy get on with their lives today, and look forward to tomorrow.



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for all forms of epilepsy

# Inside the triangle of trust.



ZITHROMAX, a macrolide antibiotic, overcomes the three-sided problem of treating children's infections.

1. Effectiveness - a 98% clinical response in otitis media<sup>1</sup> or tonsillitis/pharyngitis<sup>2</sup>
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3. Simplicity - a once daily, 3 day course that is convenient for parent and child.

It is this three-sided approach that makes ZITHROMAX so suitable for children's infections.

And that's why, when you treat with ZITHROMAX, you put children inside the triangle of trust.

## Zithromax<sup>\*</sup>

azithromycin

### Once daily for just 3 days

**ZITHROMAX<sup>\*</sup> Abbreviated Prescribing Information:** Presentation: Capsules containing 250mg azithromycin. Powder for oral suspension containing 200mg/5ml azithromycin after reconstitution. **Indications and dosage:** Upper and lower respiratory tract infections, skin and soft tissue infections and otitis media: 500mg once daily for 3 days. Uncomplicated sexually transmitted diseases caused by *Chlamydia trachomatis*: Single 1g dose. **Use in the elderly:** Normal adult dosage is recommended. **Use in children:** Once daily for 3 days. Less than 3 years (up to 15kg), 10mg (0.25ml) per kg per day; 3-7 years, 5ml per day; 8-11 years, 7.5ml per day; 12-14 years, 10ml per day. There is no information on children under six months of age. See data sheet for further information on dosage recommendations according to age and weight range. **Administration:** ZITHROMAX should be administered as a single daily dose at least 1 hour before or 2 hours after food. ZITHROMAX oral suspension should be administered to children using the spoon provided in the packs, or the oral dosing syringe provided in the 15ml pack only. Refer to data sheet for appropriate pack size and dispensing instructions. **Contra-indications:** Hypersensitivity to azithromycin or other macrolide antibiotics. Patients receiving ergot derivatives. **Warnings and Precautions:** Moderate or severe renal impairment (creatinine clearance <40ml/min), liver impairment. Pregnancy and lactation: Not recommended. **Drug Interactions:** Antacids, ergot derivatives. Monitor patients on concurrent warfarin, digoxin or cyclosporin. **Side-Effects:** Nausea, abdominal discomfort, vomiting, flatulence, diarrhoea and loose stools. Allergic reactions of rash and rare reports of angioneurotic oedema and anaphylaxis; elevation in liver transaminases and reduction in neutrophil counts. **Legal Category:** POM. **Package quantities and Basic NHS Cost:** 250mg capsule: pack of 6, £13.43; pack of 4, £8.95 (PL 0057/0335); powder for oral suspension: 15ml bottle (600mg), £5.08; 22.5ml bottle (900mg), £7.62; 30ml bottle (1200mg), £13.80 (PL 0057/0336). Hospital prices are available on request. **References:** 1. Mohs E et al. (1993) *J Antimicrob Chemother*; 31 (Suppl E): 73-79. 2. Hamill J. (1993) *J Antimicrob Chemother*; 31 (Suppl E): 89-94. 3. Hopkins S. (1993) *J Antimicrob Chemother*; 31 (Suppl E): 111-117. Further information is available on request from Richborough Pharmaceuticals, A Division of Pfizer Ltd, Sandwich, Kent CT13 9NJ. <sup>\*</sup>Trademark

  
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# Meet our top consultants



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And the result is the new **Genotropin®** Pen - we've made it easier to use, even for small children, and that makes it easier for them to keep to their treatment.

## **New Genotropin® Pen** somatropin (rbe)

*Designed by kids. Made real by Pharmacia.*

**Genotropin® (somatropin, rbe) Abbreviated Prescribing Information.** **Genotropin 36 IU, Genotropin 16 IU, Genotropin 4 IU KabiVial Multidose, Genotropin 2, 3, and 4 IU KabiQuick.** **Presentation: Genotropin 36 IU** Two compartment cartridge for use in either the Genotropin Pen 36 or KabiMixer devices. One compartment contains 36 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections. **Genotropin 16 IU** Two compartment cartridge for use in either the Genotropin Pen 16 or KabiMixer devices. One compartment contains 16 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections. **Genotropin 4 IU KabiVial Multidose** Two compartment cartridge in a reconstitution device. The first compartment contains 4 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.3% m-cresol in 1ml Water for Injections. **Genotropin 2, 3 and 4 IU KabiQuick** Two compartment cartridge in single dose syringe for reconstitution and injection. The first compartment contains 2, 3 or 4 IU somatropin (rbe) in the form of a sterile lyophilised powder. The second compartment contains 0.5ml, 0.75ml or 1ml Water for Injections respectively. **Uses:** Treatment of growth disturbance due to insufficient secretion of growth hormone or associated with gonadal dysgenesis (Turner Syndrome). Treatment of growth disturbance in prepubertal children with chronic renal insufficiency (CRI). **Dosage and Administration: Route of Administration:** Subcutaneous injection. Dosage is individual. **Insufficient secretion of growth hormone:** generally a dose of 0.5 - 0.7 IU/kg body weight per week (14 - 20 IU/m<sup>2</sup> body surface area per week) is recommended. Higher doses have been used. **Gonadal dysgenesis (Turner Syndrome):** a dose of 1 IU/kg body weight per week (28 IU/m<sup>2</sup> body surface area per week) is recommended. **CRI:** a dose of 30 IU/m<sup>2</sup> body

surface area per week (approximately 1 IU/kg body weight per week) is recommended. Higher doses may be needed if growth velocity is too low. Dose correction may be required after six months treatment. The weekly dose should be divided into 6-7 subcutaneous injections. The injection site should be varied to prevent lipatrophy. **Preparation of Solution:** Somatropin (rbe) is reconstituted using the KabiMixer, KabiVial, KabiQuick or Genotropin Pen devices. Instructions on how to effect reconstitution are supplied separately at the specialist growth clinic, as are the Genotropin Pen and KabiMixer devices, and necessary needles. **Contra-indications, Warnings etc.:** Genotropin should not be used when there is any evidence of tumour activity. Intracranial lesions must be inactive and any antitumour therapy completed prior to starting therapy. Genotropin should not be used for growth promotion in patients with closed epiphyses. **Precautions:** Therapy with Genotropin should be initiated by suitably qualified physicians. In diabetes mellitus, insulin dosage may need adjustment. Thyroid function may be affected and should be monitored periodically. In patients with endocrine disorders, slipped epiphyses of the hip may occur. Some rare cases of benign intracranial hypertension have been reported. In chronic renal insufficiency, renal function should have decreased to below 50 per cent of normal and disturbed growth followed for a year preceding institution of therapy. Conservative treatment for renal insufficiency should have been established and should be maintained during treatment. Treatment should be discontinued after renal transplantation. **Pregnancy and Lactation:** Clinical experience of use in pregnancy is limited. Treatment should be interrupted if pregnancy occurs. **Overdosage:** Acute overdosage is unlikely, though may lead initially to hypoglycaemia and subsequently to hyperglycaemia. Long-term overdosage could result in symptoms consistent with the known effects of growth hormone excess. **Side Effects:** Common effects are related to transient local skin reactions.

**Pharmaceutical Precautions:** Store at 2 - 8°C. Protect from light. Once reconstituted Genotropin should be stored in the refrigerator and protected from light. Genotropin 36 IU, Genotropin 16 IU and Genotropin 4 IU KabiVial Multidose in use may be stored for up to 14 days under these conditions. Once reconstituted Genotropin 2, 3 and 4 IU KabiQuick should be used immediately, or within 24 hours if kept in the refrigerator. **Legal Category:** POM. **Package Quantities:** Genotropin 36 IU Pack containing one cartridge for use in the Genotropin Pen 36/KabiMixer devices. Genotropin 16 IU Pack containing one cartridge for use in the Genotropin Pen 16/KabiMixer devices. Genotropin 4 IU KabiVial Multidose Two compartment cartridge in a reconstitution device. Pack containing one Genotropin 4 IU KabiVial Multidose. Genotropin 2,3 and 4 IU KabiQuick Two compartment cartridge in a reconstitution and injection device. Pack containing ten Genotropin 2 IU KabiQuicks. Pack containing ten Genotropin 3 IU KabiQuicks. Pack containing ten Genotropin 4 IU KabiQuicks. **Product Licence Numbers and Basic NHS Prices:** 36 IU - 0022/0098, 1 x 36 IU - £274.50. 16 IU - 0022/0085, 1 x 16 IU - £122.00. 4 IU KabiVial Multidose - 0022/0088, 1 x 4 IU - £30.50. 2 IU KabiQuick - 0022/0089, 10 x 2 IU - £160.00. 3 IU KabiQuick - 0022/0090, 10 x 3 IU - £240.00. 4 IU KabiQuick - 0022/0091, 10 x 4 IU - £320.00. **Product Licence/Product Authorisation Holder:** Pharmacia Ltd., Davy Avenue, Milton Keynes, MK5 8PH. Distributed in Ireland by Cahill May Roberts Ltd. for Pharmacia Ireland Ltd., Pharmapark, Chapelizod, Dublin 20. Further information is available on request from the Product Licence holder. Genotropin, KabiMixer, KabiVial and KabiQuick are registered trademarks. **Date of preparation:** November 1995. P2346/9/95

  
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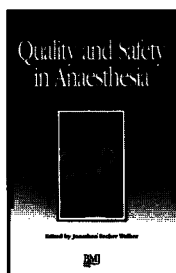
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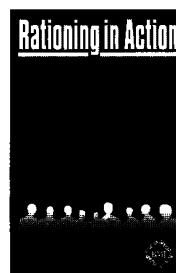
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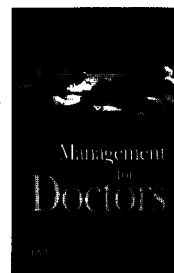
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#### PRESCRIBING INFORMATION

**Presentations:** Pulmicort Respules. 2ml single dose unit ampoules containing 0.25mg/ml or 0.5mg/ml budesonide in a suspension for nebulisation. **Uses:** Bronchial asthma where use of a pressurised inhaler or dry powder formulation is unsatisfactory or inappropriate. Pulmicort Respules are also recommended for use in infants and children with acute laryngotracheobronchitis - croup. **Dosage and administration:** Dosage schedules: Administer from suitable nebulisers. Dose delivered to the patient varies depending on the nebulising equipment used (see data sheet). **Bronchial asthma.** Adjust dosage individually. Initially during periods of severe asthma and while reducing or discontinuing oral glucocorticosteroids the recommended dose in adults (including elderly and children 12 years and older) is usually 1-2mg twice daily. In very severe cases, the dosage may be further increased. Children 3 months to 12 years: 0.5-1mg twice daily. The maintenance dose should be the lowest dose which keeps the patient symptom-free. Recommended doses are: Adults (including elderly and

children 12 years and older): 0.5-1mg twice daily. Children (3 months to 12 years): 0.25-0.5mg twice daily. For an increased therapeutic effect increase dose of Pulmicort rather than combine treatment with oral corticosteroids because of the lower risk of systemic effects. **Acute laryngotracheobronchitis - croup.** In infants and children with croup the usual dose is 2mg of nebulised budesonide. This dose is given as a single administration or as two 1mg doses separated by 30 minutes. **Contra-indications, warnings, etc.:** Contra-indications: Hypersensitivity to any of the constituents. Special warnings and precautions: Care is needed in patients with pulmonary tuberculosis and viral infections in the airways. A short course of oral steroids in addition to Pulmicort may be required in patients with excessive mucus in the bronchi. Transfer of patients dependent on oral steroids to Pulmicort demands special care; see data sheet for further details. The nebuliser chamber should be cleaned and dried after every administration. Pulmicort does not affect the ability to drive and use machines. Pulmicort Respules can be mixed with 0.9% saline and with solutions

of terbutaline, salbutamol, sodium cromoglycate or ipratropium bromide. **Side-effects:** Mild irritation in the throat, coughing and hoarseness and oral candidiasis have been reported. In rare cases inhaled drugs may provoke bronchoconstriction in hyperreactive patients. Facial skin should be washed after use of the face mask as irritation can occur. Coughing can usually be prevented by inhaling a  $\beta_2$ -agonist (e.g. terbutaline) 5-10 minutes before inhalation of Pulmicort Respules. Avoid in pregnancy. **Pharmaceutical precautions:** Store below 30°C. Use within 3 months of opening the foil envelope. Protect opened ampoule from light. Use within 12 hours of opening. **Legal status:** POM. **Basic NHS price:** Pulmicort Respules 0.25mg/ml (20 single dose units) £32.00. Pulmicort Respules 0.5mg/ml (20 single dose units) £44.64. **Product licence nos.:** Pulmicort Respules 0.25mg/ml PL 0017/0309. Pulmicort Respules 0.5mg/ml PL 0017/0310. **Name and address of Product Licence holder:** Astra Pharmaceuticals Ltd. Home Park, Kings Langley, Herts WD4 8DH.

# First licensed treatment for croup



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**Pulmicort**<sup>®</sup>  
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BUDESONIDE

Medical Information Services 01923 266191 during office hours.