

# The CF World has been turning to Creon for years



**creon**<sup>®</sup>  
pancreatin



Because CF patients need all the help they can get

#### PRESCRIBING INFORMATION

**Presentation** 1. Creon - brown/yellow capsules containing enteric coated granules of pancreatin, equivalent to: 8,000 PhEur units of lipase; 9,000 PhEur units of amylase and 450 PhEur units (total) of protease (210 BP units). Available in packs of 100. Basic NHS price of £13.33. PL 5727/0001. 2. Creon sachets - unit dose sachets containing enteric coated granules of pancreatin, equivalent to: 20,000 PhEur units of lipase, 22,500 PhEur units of amylase and 1,125 PhEur units (total) of protease. Available in packs of 40. Basic NHS price of £13.33. PL 5727/0007.

**Indication** Pancreatic exocrine insufficiency.

**Dosage and Administration:** Adults and children: 1. Creon - initially one or two capsules with meals, then adjust according to response. 2. Creon sachets - initially the contents of one sachet with meals, then adjust according to response. (Note that two sachets of Creon granules are equivalent to five capsules of Creon.) The contents of each sachet can be taken from a spoon or tipped directly onto the tongue, and then washed down with a drink of water or other fluid. The granules contained in Creon capsules or sachets can also be sprinkled on soft food, which should then be

swallowed without chewing. If the granules are mixed with food, it is important that they are taken immediately, otherwise dissolution of the enteric coating may result.

**Contra-indications, Warnings etc. Contra-indications:** substitution with pancreatic enzymes is contra-indicated in the early states of acute pancreatitis. Use in pregnancy: there is inadequate evidence of safety in use during pregnancy. **Warnings:** The product is of porcine origin. Rarely cases of hyper-uricosuria and hyper-uricaemia have been reported with very high doses of pancreatin. Perianal irritation, and rarely, inflammation, could occur when large doses are used.

**Legal Classification:** P

**Name and Address of Licence Holder:** Kali Chemie Pharma GmbH, Postfach 220, D-30173, Hannover 1, Germany.

**Further information available from:** Duphar Laboratories Limited, Gaters Hill, West End, Southampton SO18 3JD. Tel: 0703 472281.

Date of preparation August 1994

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THIRD EDITION



By  
**JOHN FEELY**

This fully revised third edition of *New Drugs* will help doctors to keep up to date with the latest developments in new and existing drugs. This invaluable guide:

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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 in divided doses increasing in steps of 200mg to a maximum dose of 2500mg per day. *Children over 20kg*; initially 400mg a day in divided doses 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 500 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** April 1995.

**References:**

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



# Give someone with epilepsy a future to look forward to

People with epilepsy have the same aspirations as anybody else. What they need is a treatment which allows them to fulfil their potential.

Whatever the type of epilepsy, Epilim Chrono can help. Effective both in generalized and partial seizures,<sup>1</sup> it is well tolerated (particularly with regard to cognitive function)<sup>2</sup>, and offers patients the convenience of once-daily dosing.\*

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



\*500mg Tablets  
**Epilim<sup>®</sup> CHRONO<sup>®</sup>**  
Sodium Valproate Ph. Eur.  
Valproic Acid Fr.P  
Controlled Release  
Once-daily management  
for all forms of epilepsy

# I used to be a mixed up kid. Now I mix up easily.



"The teachers treated me like a baby. The other kids teased me and called me 'shorty'. And on top of all that, I had to have nasty injections all the time."

Because life can be complicated enough for children with growth hormone deficiency, the KabiPen® is the straightforward choice. With the Pen, there's no need to worry about preparing and mixing the powder and diluent before every injection.

All a child has to do is load a Genotropin® cartridge into the Pen and then inject. The mixing takes place automatically within the two-compartment cartridge.

No more fiddly mixing by hand. It's one thing less to worry about in life. Why complicate growing up?

# Genotropin®

somatropin (rbe)

**Prescribing Information** Genotropin 36 IU. **Presentation** Genotropin: 36 IU Two-compartment cartridge for use in the KabiPen 36 device. 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 of Water for Injections. **Uses:** The treatment of short stature due to decreased or absent secretion of pituitary growth hormone. The diagnosis should be verified by a specialist medical practitioner. The treatment of short stature in gonadal dysgenesis (Turner syndrome). **Dosage and Administration:** Route of Administration: By subcutaneous injection. Recommended dosage: The dosage is individual. Generally a dose of 0.5-0.7 IU/kg body weight per week is recommended. In Turner Syndrome a dose of 1.0 IU/kg body weight per week is recommended. Preferably the weekly dose should be divided into six or seven daily subcutaneous injections. The injection site should be varied to prevent lipotrophy. **Preparation of solution:** Somatropin (rbe) is reconstituted using the KabiPen device. Instructions on how to effect reconstitution are supplied separately at the specialist growth clinic, as is the KabiPen device. **Contra-indications, Warnings etc:** Only patients with unfused epiphyses should be treated. Genotropin should not be used when evidence of tumour activity exists; intracranial lesions must be inactive and antitumour therapy completed before treatment begins. Treatment with these products should be discontinued when there is evidence of tumour growth. **Precautions:** Patients with diabetes mellitus may require adjustment of their antidiabetic therapy. Patients treated with Genotropin should be regularly assessed by a specialist in child growth. This assessment should include accurate determination of the growth response and endocrinological status, as relative deficiencies of other pituitary hormones may be exposed or exacerbated by an adequate growth response. Hypothyroidism in particular is a reported occurrence. Some cases of acute leukaemia have been reported in growth hormone deficient children untreated as well as treated with growth hormone and might possibly represent a slightly increased incidence compared with non growth hormone deficient children. A causal relationship to growth hormone therapy has not been established. **Pregnancy and lactation:** Treatment should be discontinued in the event of a pregnancy occurring during therapy with Genotropin, as there is no evidence from either human or animal studies of the safety of growth hormone treatment during pregnancy. No information is available as to whether peptide hormones pass into breast milk, but the quantities involved would not have any clinical effect on the infant. **Overdosage:** Acute overdosage is unlikely and does not represent a hazard to the patient. The consequences of long-term administration of doses above the therapeutic range are unknown. **Side-effects:** Recipients may develop antibodies to growth hormone and E.coli protein. However, as with pituitary-derived hormone, only in rare instances has growth retardation occurred. Reactions at the site of injection have been reported, such as itching, lumps, redness and lipotrophy. Lipotrophy can be prevented or minimised by varying the injection site. In Turner Syndrome temporary exacerbation of lymphoedema has been reported. **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, may be stored for up to 14 days under these conditions. **Legal Category:** POM **Package quantities:** Genotropin 36 IU: Pack containing one cartridge for use in the KabiPen 36 device. **Further information:** Somatropin (rbe) is the British Approved Name for recombinant human somatotropin. **Product Licence Number:** 0022/0098, 1 x 36 IU. **Basic NHS Price:** £274.50. **Product Licence Holder:** Pharmacia Ltd, Davy Avenue, Milton Keynes, Bucks MK5 8PH. Further information is available on request from the Product Licence holder. Genotropin and KabiPen are registered trademarks. **Date of preparation:** June 1995.



Pharmacia

**BREVETED PRESCRIBING INFORMATION**  
 UNIPHYLLIN CONTINUS tablets contain theophylline BP in a controlled release system. UNIPHYLLIN CONTINUS tablets 400 mg are white, capsule-shaped, scored tablets with the logo NAPP U400 bossed on one side and UNIPHYLLIN on the other. UNIPHYLLIN CONTINUS tablets 300 mg are white, capsule-shaped, scored tablets with U300 embossed on one side and UNIPHYLLIN on the other. UNIPHYLLIN CONTINUS tablets 200 mg are white, capsule-shaped, scored tablets with U200 bossed on one side. Uses Theophylline is a bronchodilator. In addition it affects the function of a number of cells involved in the inflammatory processes associated with asthma and chronic obstructive airways disease. Of most importance may be enhanced suppressor lymphocyte activity and reduction of eosinophil and neutrophil function. These actions may contribute to anti-inflammatory prophylactic activity in asthma and chronic obstructive airways disease. For the treatment and prophylaxis of bronchospasm associated with asthma, emphysema and chronic bronchitis. Also indicated in adults for the treatment of cardiac asthma and left ventricular or congestive cardiac failure. Dosage and administration: **Adults:** Tablets should be swallowed whole and not chewed. Tablets: The usual maintenance dose for elderly patients or those less than 70 kg body weight is 200 mg, 12-hourly following an initial week of therapy on 200 mg, 12-hourly. The usual maintenance dose for patients of 70 kg body weight or over is 400 mg, 12-hourly following an initial week of therapy on 200 mg or 0 mg, 12-hourly. **Children:** Not recommended for children under seven years of age. The maintenance dose is 9 mg/kg twice daily. Some children with chronic asthma require and tolerate much higher doses (10-16 mg/kg twice daily). Lower dosages (based on usual adult dose) may be required by adolescents. It may be appropriate to administer a larger evening or morning dose in some patients, in order to achieve optimum therapeutic effect when symptoms are quite severe, e.g. at the time of the 'morning dip' in lung function. In patients whose night time or day time symptoms persist despite other therapy and who are not currently receiving theophylline, then the total daily requirement of UNIPHYLLIN CONTINUS tablets (as specified above) may be added to their treatment regimen as either a single evening or morning dose. **Elderly:** The initial dose should be 200 mg, 12-hourly increasing to 300 mg, 12-hourly. **Contra-indications:** Should not be given concomitantly with ephedrine in children. **Precautions and warnings:** Clearance may increase and it may therefore be necessary to increase dosage to ensure a therapeutic effect: phenytoin, carbamazepine, rifampicin, sulphamonomethoxazole and barbiturates. Smoking and alcohol consumption can also increase clearance of theophylline. In patients following reduce clearance and a reduced dosage may therefore be necessary to avoid side-effects: allopurinol, cimetidine, ciprofloxacin, erythromycin, thiazolidine, isoprenaline, fluvoxamine, viloxazine hydrochloride and oral contraceptives. Factors such as viral infections, liver disease and heart failure also reduce theophylline clearance. **Side-effects:** The hypokalaemia resulting from theophylline therapy may be exacerbated by diuretics.

significantly reduced when UNIPHYLLIN CONTINUS tablet preparations are given. Furthermore, the side effects can be minimised by dose titration downwards. **Transferability:** It is not possible to ensure bioequivalence between different sustained release theophylline products. Therefore, it should be emphasised that patients, once titrated to an effective dose, should not be changed from UNIPHYLLIN CONTINUS tablet preparations to other slow or sustained release theophylline preparations without re-titration and clinical assessment. **Legal category:** P. **Package quantities and prices:** NHS price UNIPHYLLIN CONTINUS tablets 400 mg - 56's: £7.32; 250's: £32.36; 1,000's: £125.29. UNIPHYLLIN CONTINUS tablets 300 mg - 56's: £6.17; 100's: £27.89. UNIPHYLLIN CONTINUS tablets 200 mg - 56's: £4.05. **Product licence numbers:** UNIPHYLLIN CONTINUS tablets 400 mg - PL 0337/0074. UNIPHYLLIN CONTINUS tablets 300 mg - PL 0337/0129. UNIPHYLLIN CONTINUS tablets 200 mg - PL 0337/0057. **Product licence holder:** Napp Laboratories Limited, Cambridge Science Park, Milton Road, Cambridge CB4 4GW, UK. Tel: 01223 424444. **Member of:** Napp Pharmaceutical Group. **Further information is available from:** Napp Laboratories Limited. © The NAPP Group. UNIPHYLLIN and CONTINUS are Registered Trade Marks. © NAPP Laboratories Limited 1995. **References:** 1. Kidney J, Dominguez M, Taylor PM, et al. (in press). Date of preparation: April 1995.

There's a new  
dimension to  
UNIPHYLLIN

For over 50 years, theophylline has been regarded as a bronchodilator. New evidence<sup>1</sup> demonstrates that this is only part of the story.

UNIPHYLLIN CONTINUS tablets are now believed to exert an anti-inflammatory action. They therefore present a convenient and acceptable choice for preventive therapy - and add a new dimension to asthma management.

DUAL ACTION

**Uniphyllin**<sup>®</sup>

CONTINUS® TABLETS THEOPHYLLINE BP

**Breathing new life into asthma therapy**

**NAPP**

**ABBREVIATED PRESCRIBING INFORMATION FOR DIFLUCAN\* (fluconazole) (UK) Presentation:** Capsules containing 50mg, 150mg or 200mg fluconazole; intravenous infusion containing fluconazole 2mg/ml in 0.9% sodium chloride solution; Powder for Oral Suspension available as two dosage strengths containing either fluconazole 50mg/5ml or 200mg/5ml on reconstitution with 24ml water. **Indications and dosage:** **Adults:** Systemic candidiasis: 400mg on the first day followed by 200-400mg once daily. Cryptococcosis, including meningitis: 400mg on the first day followed by 200-400mg once daily. Maintenance therapy to prevent relapse of cryptococcal meningitis in patients with AIDS: 100-200mg daily. Oropharyngeal candidiasis: 50-100mg once daily for 7-14 days or longer in immunocompromised patients. Other mucosal candidal infections: 50-100mg once daily for 14-30 days. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 50-400mg once daily based on patient's risk for developing fungal infection. For patients at high risk of systemic infection, eg patients who are anticipated to have profound or prolonged neutropenia such as during bone marrow transplantation, the recommended dose is 400mg daily. Start dosage several days before anticipated onset of neutropenia and continue for seven days after neutrophil count rises above 1000 cells per mm<sup>3</sup>. Dermal fungal infections: 50mg once daily for up to 6 weeks (usually 2-4 weeks - see data sheet). Vaginal candidiasis: Single 150mg dose. Use in the elderly - as above except for those renally impaired - see data sheet. **Children: Over 4 weeks old:** Mucosal candidiasis: 3mg/kg daily. A loading dose of 6mg/kg may be used on the first day. Systemic candidiasis and cryptococcal infection: 6-12mg/kg daily depending on severity of disease. Prevention of fungal infections in neutropenic patients following cytotoxic chemotherapy or radiotherapy: 3-12mg/kg daily depending on the extent and duration of the neutropenia. **Children below 4 weeks of age:** First two weeks of life: The same mg/kg dosing as above but administered every 72 hours. During weeks 2-4 of life same mg/kg dose should be given every 48 hours. Doses of less than 10mg fluconazole should only be administered in hospital. A suitable measuring device should be used for administration of the suspension. **Administration:** DIFLUCAN may be administered either orally or by intravenous infusion at a rate of approximately 5-10ml/min. The dosages for the two routes are equivalent. **Contra-indications:** Hypersensitivity to fluconazole or related azoles, pregnancy and women of childbearing potential unless adequate contraception is employed. **Warnings:** Lactation: Not recommended. Renal impairment: Dosage reduction in both adults and children may be necessary, see data sheet. **Drug interactions:** Anticoagulants, cyclosporin, oral sulphonylureas, phenytoin, rifampicin and theophylline. **Side-effects:** Nausea, abdominal discomfort, diarrhoea, flatulence and rarely anaphylaxis. **Legal Category:** POM. **Basic NHS Cost and Package Quantities:** DIFLUCAN capsules in calendar packs containing 7x50mg (£16.61, PL 57/0289), 7x200mg (£66.42, PL 57/0317) or 1x150mg (£7.12, PL 57/0290); Powder for Oral Suspension, 35ml bottle of 50mg/5ml (£16.61, PL 57/0343), 35ml bottle of 200mg/5ml (£66.42, PL 57/0344); Intravenous Infusion: 25ml (50mg) bottle (£7.32, PL 57/0315); 100ml (200mg) bottle (£29.28, PL 57/0315). Hospital prices are available on request. † DIFLUCAN is well tolerated with few adverse effects: Marchisio P *et al.* (1994) *Eur J Clin Microbiol Infect Dis* 13: 338-340. Fasano C *et al.* (1994) *Eur J Clin Microbiol Infect Dis* 13: 344-347. Further information on request. \* Trade Mark. Pfizer Limited, Sandwich, Kent. 51336 March 1995.

**HITS CHILDREN'S  
FUNGAL INFECTIONS**

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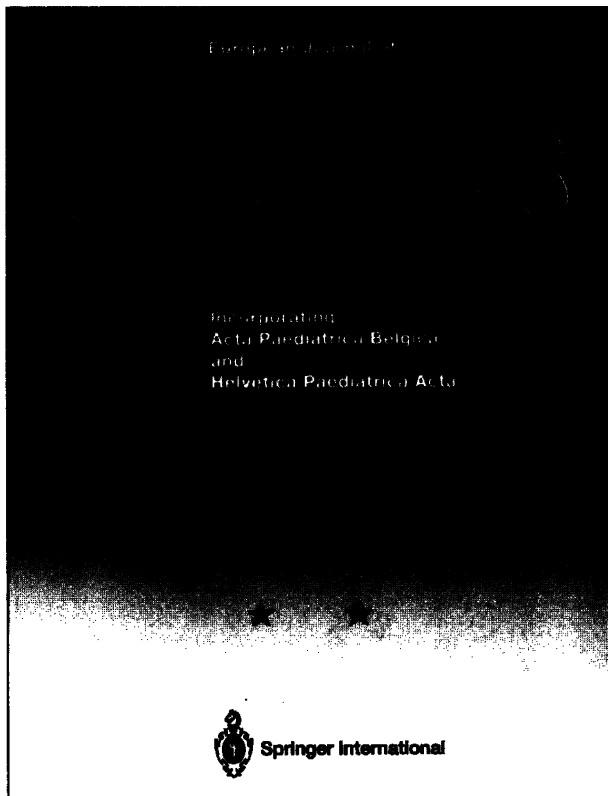
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fluconazole

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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. **Dosage and administration:** Dosage schedules: Administer from suitable nebulisers. Dose delivered to the patient varies depending on the nebulising equipment used (see data sheet). 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. **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.

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

Nebulised Steroid Control