form; Diprosalic; Dovobet; Ecoval con Neomicina; Egerian; Eubetal Antibiotico, Fidagenbeta; Fluoroninil; Fucicort; Gentalyn Beta; Kamelyn, Micutrin Beta†; Psonnase†; Rinojet†; Steroznil; Stranoval; Toker, Visublefarite; Visumetazone Antibiotico; *Malaysia*: Axcel Fusi-Corte; B-Mycin; Beavate N; Beprogent; Beprosalic; Besone-N; Betacin; Betagen; Betamethasone Cio; Betamethasone G; Betamethasone N; Betnovate-N; Celestoderm-V with Garamycin†; Diprogenta; Diprosalic; Polanort; Fucicort; Fusidis B; Garasone; Joysur, Tinderm-C; Uniflex-N†; *Mex.*: Artridol; Barmicil Compuesto; Beclogen; Betrigen; Celestamine NS; Celestamine-F†; Celestamine†; Claricort†; Clo-Betnovate; Clotricina; Daivobet; Diprosalic†; Diprosalic; Diprosalo; Clotricina; Daivobet; Diprosalic†; Diprosalic; MZ: Betnesol Aqueous; Betnovate—Clotricina; Diavobet; Diprosalic; Pucicort; Lotricomb†; Philipp. Betneston; Betnovate—C; Daivobet; Diprosalic†; Pucicort; Claricort; Clotrisone; Daivobet; Diprosalic†; Pucicort; Clotricomb†; Philipp. Betnesor; Betnovate-C; Betnovate-N; Celestamine; Claricort; Glotrisone; Daivobet; Diprosalic†; Pucicort; Clotricomb†; Philipp. Betnesor; Betnovate-C; Betnovate-N; Daivobet; Diprosalic; Pucicort; Pof.: Bedicort G; Betnovate-C; Betnovate-C; Betnovate-N; Daivobet; Diprosalic; Polanort; Diprosalic; Diprosalic; Diprosalic

# **Budesonide** (BAN, USAN, rINN) ⊗

Budesonide; Budesonida; Budesonide; Budesonidi; Budesonidim; Budesonid; Budezonidas; S-I 320. An epimeric mixture of the  $\alpha$ - and  $\beta$ -propyl forms of  $16\alpha$ ,17 $\alpha$ -butylidenedioxy-I I  $\beta$ ,21-dihydroxypregna-I,4-diene-3,20-dione.

Будезонид

 $C_{25}H_{34}O_6 = 430.5$ 

CAS — 51333-22-3 ( $11\beta,16\alpha$ ); 51372-29-3 ( $11\beta,16\alpha(S)$ ); 51372-28-2 ( $11\beta,16\alpha(S)$ ).

ATC — A07EA06; D07AC09; H02AB16; R01AD05; R03BA02.

ATC Vet — QA07EA06; QD07AC09; QR01AD05; QR03BA02.

**Pharmacopoeias.** In Eur. (see p.vii) and US.

Ph. Eur. 6.2 (Budesonide). A white or almost white, crystalline powder. Practically insoluble in water; sparingly soluble in alcohol; freely soluble in dichloromethane.

**USP 31** (Budesonide). A white to off-white, odourless, crystalline powder. Practically insoluble in water and in heptane; sparingly soluble in alcohol; freely soluble in chloroform. Store in airtight containers at a temperature of 20° to 25°, excursions permitted between 15° and 30°. Protect from light.

# Adverse Effects, Treatment, Withdrawal, and Precautions

As for corticosteroids in general (see p.1490).

Inhalation of high doses of budesonide is associated with some adrenal suppression. Systemic absorption may follow nasal use, particularly after high doses or prolonged treatment. The dose of oral budesonide may need to be reduced in hepatic impairment (see also Administration in Hepatic Impairment, below).

When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, or when given intranasally, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.

**Effects on the bones.** For mention of the effects of inhaled budesonide on markers of collagen turnover and bone density in asthmatic children, see under Adverse Effects of Beclometasone, p.1516. For the suggestion that inhalation once-daily in the morning may have less marked effects on growth and collagen turnover than twice-daily inhalation, see Administration, below.

**Effects on the nervous system.** Psychotic behaviour has been reported after use of inhaled budesonide. <sup>1-3</sup>

- Lewis LD, Cochrane GM. Psychosis in a child inhaling budesonide. Lancet 1983; ii: 634.
- Meyboom RHB, de Graff-Breederveld N. Budesonide and psychic side effects. Ann Intern Med 1988; 109: 683.
- Connett G, Lenney W. Inhaled budesonide and behavioural disturbances. Lancet 1991; 338: 634–5.

Hypersensitivity. Contact dermatitis has been reported to topical or intranasal budesonide. An anaphylactoid reaction occurred 5 minutes after the first dose of oral budesonide in a patient who had previously reacted in a similar way to mesalazine.<sup>2</sup>

- Quintiliani R. Hypersensitivity and adverse reactions associated with the use of newer intranasal corticosteroids for allergic rhinitis. Curr Ther Res 1996; 57: 478–88.
- Heeringa M, et al. Anaphylactic-like reaction associated with oral budesonide. BMJ 2000; 321: 927.

#### **Interactions**

The interactions of corticosteroids in general are described on p.1494.

### **Pharmacokinetics**

For a brief outline of the pharmacokinetics of corticosteroids, see p.1495. Budesonide is rapidly and almost completely absorbed after oral administration, but has poor systemic availability (about 10%) due to extensive first-pass metabolism in the liver, mainly by the cytochrome P450 isoenzyme CYP3A4. The major metabolites, 6- $\beta$ -hydroxybudesonide and 16- $\alpha$ -hydroxyprednisolone have less than 1% of the glucocorticoid activity of unchanged budesonide. Budesonide is reported to have a terminal half-life of about 2 to 4 hours.

♦ Reviews.

- Donnelly R, Seale JP. Clinical pharmacokinetics of inhaled budesonide. Clin Pharmacokinet 2001; 40: 427–40.
- Edsbäcker S, Andersson T. Pharmacokinetics of budesonide (Entocort EC) capsules for Crohn's disease. Clin Pharmacokinet 2004; 43: 803–21.
- Kraft WK, et al. The pharmacokinetics of nebulized nanocrystal budesonide suspension in healthy volunteers. J Clin Pharmacol 2004; 44: 67–72.
- Lähelmä S, et al. Equivalent lung deposition of budesonide in vivo: a comparison of dry powder inhalers using a pharmacokinetic method. Br J Clin Pharmacol 2005; 59: 167–73.

## **Uses and Administration**

Budesonide is a corticosteroid with mainly glucocorticoid activity (p.1490). It is used by inhalation in the management of asthma, in usual doses of 400 micrograms daily in 2 divided doses from a metered-dose aerosol; in severe asthma the dosage may be increased up to a total of 1.6 mg daily, and guidelines for the management of asthma permit up to 2 mg daily (see p.1108). Maintenance doses may be less than 400 micrograms daily but should not be below 200 micrograms daily. A dose for children is 50 to 400 micrograms inhaled twice daily. Budesonide is also available for the management of asthma in the form of a dry powder inhaler; doses are 200 to 800 micrograms daily, as 2 divided doses or a single daily dose; up to 800 micrograms twice daily may be given to adults if necessary. Patients for whom budesonide from a pressurised inhaler or dry powder formulation is unsatisfactory may use a nebulised solution. The usual adult dosage by this method is 1 to 2 mg inhaled twice daily. This may be increased if asthma is severe. Maintenance doses are 0.5 to 1 mg inhaled twice daily. For children between 3 months and 12 years of age, an initial dose is 0.5 to 1 mg twice daily with a maintenance dose of 0.25 to 0.5 mg twice daily.

Budesonide is also given by inhalation as a nebulised solution in the management of childhood **croup** (p.1502). The usual dose is 2 mg, as a single inhaled dose or 2 doses of 1 mg, given 30 minutes apart.

Budesonide is used topically in the treatment of various **skin disorders**, as a cream, lotion, or ointment containing 0.025%. For recommendations concerning the correct use of corticosteroids on the skin, and a rough guide to the clinical potencies of topical corticosteroids, see p.1497.

Budesonide is also used intranasally for the prophylaxis and treatment of **rhinitis** (p.565). In the UK, two nasal spray preparations are available, one containing 100 micrograms per metered spray, and one containing 64 micrograms per metered spray. The initial recommended dose for adults and children over 12 years is either 2 sprays into each nostril once daily in the morning, or 1 spray into each nostril twice daily. This may be subsequently reduced to 1 spray into each nostril once daily: treatment can be continued for up to 3 months. In the USA and some other countries, a nasal spray and a nasal inhaler are available. The intranasal dose may be expressed in multiples of 32 micrograms, which is the quantity of budesonide delivered from the nasal adaptor. When given from a nasal inhaler, the recommended initial dose for adults and children over 6 years is 4 sprays into each nostril in the morning, or 2 sprays into each nostril twice daily, to give a total daily dose of 256 micrograms daily. This is reduced to the lowest dose adequate to control symptoms. If no benefit is seen after 3 weeks of treatment, budesonide should be stopped. When given as an aqueous nasal spray, the recommended initial dose for adults and children over 6 years is 1 spray into each nostril once daily (64 micrograms daily), increasing as necessary up to a maximum of 256 micrograms daily for adults and 128 micrograms daily for children aged less than 12 years. Budesonide is also used as a nasal spray in the management of **nasal polyps** (p.1508). In the UK, for adults and children over 12 years, 1 spray (containing 64 or 100 micrograms, as above) is given into each nostril twice daily for up to 3 months.

Local formulations of budesonide are used in the management of inflammatory bowel disease (see below). In mild to moderate Crohn's disease affecting the ileum or ascending colon it is given orally as modifiedrelease capsules intended for a topical effect on the gastrointestinal tract. The recommended dose is 9 mg daily for active disease, as either a single dose before breakfast or in 3 divided doses about 30 minutes before meals, depending on the preparation. Treatment is given for up to 8 weeks, and the dosage should be reduced 2 to 4 weeks before discontinuing therapy. For recurring episodes of active Crohn's disease, an 8-week course may be repeated. After an 8-week course for active disease, budesonide 6 mg once daily is recommended for maintenance of clinical remission, for up to 3 months; thereafter, doses are tapered and therapy stopped, as continued treatment has not shown substantial clinical benefit. There is some absorption of budesonide from the gastrointestinal tract, and the dose may need to be reduced in patients with hepatic impairment, especially those with cirrhosis (see also Administration in Hepatic Impairment, below). Ulcerative colitis affecting the rectum and sigmoid colon may be treated locally with budesonide. A retention enema providing a dose of 2 mg in 100 mL is given daily at bedtime for 4 weeks, which may be extended to 8 weeks if the patient is not in remission after the initial 4-week course. Alternatively, a rectal foam can be used in a dose of 2 mg once daily, usually for 6 to 8 weeks. The dose may be given in the morning or the evening, but treatment is more effective if the bowel is emptied before a dose is given.

Local formulations of budesonide are also used in the management of collagenous colitis (see below). It is given orally as modified-release capsules in a dose of 3 mg three times daily for up to 8 weeks. The dosage should be reduced gradually during the last 2 weeks of therapy.

♦ General references.

- 1. Brogden RN, McTavish D. Budesonide: an updated review of its pharmacological properties, and therapeutic efficand rhinitis. *Drugs* 1992; **44:** 375–407 and 1012. efficacy in asthma
- Hvizdos KM, Jarvis B. Budesonide inhalation suspension: a review of its use in infants, children and adults with inflammatory respiratory disorders. Drugs 2000; 60: 1141-78.
- Stanaland BE. Once-daily budesonide aqueous nasal spray for allergic rhinitis: a review. Clin Ther 2004; 26: 473–92.

Administration, INHALATIONAL ROUTE. One study in 6 children aged up to 30 months found that about 75% of the nominal dose of nebulised budesonide was deposited in the nebuliser system,1 while a study in 126 older children indicated that maintenance doses of budesonide could be halved when the dose was given by dry powder inhaler rather than nebuliser, without any loss of asthma control.2 Although oropharyngeal deposition is thought to play a role in the systemic effects of inhaled corticosteroids, another study<sup>3</sup> indicated that only about 20% of the systemically available drug appeared to be derived from oropharyngeal deposition after inhalation from a dry powder inhaler.

There is evidence that the timing of inhaled therapy might influence some systemic effects. A study<sup>4</sup> in children with mild asthma found that 800 micrograms of budesonide inhaled in the morning had less effect on measurements of short-term growth and collagen turnover than inhalation of 400 micrograms twice daily.

- Carlsen KCL, et al. How much nebulised budesonide reaches infants and toddlers? Arch Dis Child 1992; 67: 1077–9.
- Agertoft L, Pedersen S. Importance of the inhalation device on the effect of budesonide. Arch Dis Child 1993; 69: 130–3.
- 3. Pedersen S, et al. The influence of orally deposited budesonide on the systemic availability of budesonide after inhalation from a Turbuhaler. Br J Clin Pharmacol 1993; 36: 211–14.
- 4. Heuck C. et al. Adverse effects of inhaled budesonide (800 micrograms) on growth and collagen turnover in children with asthma: a double-blind comparison of once-daily versus twice-daily administration. *J Pediatr* 1998; **133**: 608–12.

Administration in hepatic impairment. In a study<sup>1</sup> of patients with primary biliary cirrhosis the clearance of oral budes onide was significantly reduced in those with cirrhosis (stage IV) compared with milder disease (stage I/II). Elevated budesonide concentrations were sufficient to suppress cortisol production, and believed to be associated with the development of portal vein thrombosis in 2 cirrhotic patients.

Hempfling W, et al. Pharmacokinetics and pharmacodynamic action of budesonide in early- and late-stage primary biliary cir-rhosis. Hepatology 2003; 38: 196–202.

Asthma. References to the use of budesonide in asthma. 1-7 Its use as a fixed-dose combination with formoterol has also been reviewed.8,9

- Baker JW, et al. A multiple-dosing, placebo-controlled study of budesonide inhalation suspension given once or twice daily for treatment of persistent asthma in young children and infants. *Pediatrics* 1999; **103**: 414–21.
- 2. The Childhood Asthma Management Program Research Group Long-term effects of budesonide or nedocromil in children with asthma. N Engl J Med 2000; **343**: 1054–63.
- Leflein JG, et al. Nebulized budesonide inhalation suspension compared with cromolyn sodium nebulizer solution for asthma in young children: results of a randomized outcomes trial. Pediatrics 2002; **109:** 866–72.
- Pauwels RA, et al. Early intervention with budesonide in mild persistent asthma: a randomised, double-blind trial. Lancet 2003; 361: 1071–6.
- 5. FitzGerald JM, et al. Doubling the dose of budesonide versus maintenance treatment in asthma exacerbations. Thorax 2004:
- 6. Berger WE, et al. Safety of budesonide inhalation suspension in infants aged six to twelve months with mild to moderate persistent asthma or recurrent wheeze. *J Pediatr* 2005; **146:** 91–5.
- 7. Berger WE. Budesonide inhalation suspension for the treatment of asthma in infants and children. Drugs 2005; 65: 1973-89.
- 8. Goldsmith DR, Keating GM. Budesonide/formoterol: a review of its use in asthma. *Drugs* 2004; **64:** 1597–1618. 9. O'Byrne PM, *et al.* Budesonide/formoterol combination therapy
- as both maintenance and reliever medication in asthma. Am J Respir Crit Care Med 2005; 171: 129-36.

Chronic obstructive pulmonary disease. For discussion of the value of inhaled corticosteroids in chronic obstructive pulmonary disease, including reference to the use of budesonide, see p.1501. The use of a fixed-dose combination of budesonide and formoterol in chronic obstructive pulmonary disease has been re-

1. Reynolds NA, et al. Budesonide/formoterol: in chronic obstructive pulmonary disease. Drugs 2004; 64: 431-41.

Collagenous colitis. Budesonide has been used in a few small controlled studies<sup>1-5</sup> of the management of collagenous colitis (see Microscopic Colitis, p.1700). Treatment courses given orally for 6 or 8 weeks were found to improve symptoms and histology, and the short-term benefits have been confirmed by metaanalysis,6 although high rates of relapse after stopping treatment have been reported.3

- 1. Baert F, et al. Budesonide in collagenous colitis: a double-blind placebo-controlled trial with histologic follow-up. Gastroenterology 2002; **122:** 20–5.
- 2. Miehlke S, *et al.* Budesonide treatment for collagenous colitis: a randomized, double-blind, placebo-controlled, multicenter trial. Gastroenterology 2002; 123: 978–84.
- 3. Bonderup OK, et al. Budesonide treatment of collagenous colitis: a randomised, double blind, placebo controlled trial with morphometric analysis. Gut 2003; 52: 248–51.
- 4. Madisch A, et al. Oral budesonide therapy improves quality life in patients with collagenous colitis. Int J Colorectal Dis 2005; **20**: 312–16.

  5. Miehlke S, *et al.* Long-term follow-up of collagenous colitis af-
- ter induction of clinical remission with budesonide. *Aliment Pharmacol Ther* 2005; **22:** 1115–19.
- Friatrinacoi Ther 2003, 22. 1113–17.
  6. Feyen B, et al. Meta-analysis: budesonide treatment for collagenous colitis. Aliment Pharmacol Ther 2004; 20: 745–9.

Cystic fibrosis. Cystic fibrosis (p.166) is associated with bronchial hyper-responsiveness; a small study1 has suggested that inhalation of budesonide 1.6 mg daily for 6 weeks improves hyperresponsiveness slightly and leads to improvement in cough and dyspnoea. A larger study<sup>2</sup> of budesonide given for two successive 3-month treatment periods found improved hyper-responsiveness and a trend towards slower decline in lung function.

- 1. Van Haren EHJ, et al. The effects of the inhaled corticosteroid budesonide on lung function and bronchial hyperresponsivenes in adult patients with cystic fibrosis. Respir Med 1995; 89: 209 - 14
- 2. Bisgaard H, et al. Controlled trial of inhaled budesonide in patients with cystic fibrosis and chronic bronchopulmonary Pseudomonas aeruginosa infection. Am J Respir Crit Care Med 1997;

Inflammatory bowel disease. Budesonide has been given as an enema for the treatment of distal ulcerative colitis, in which context its potency and low systemic availability are advantageous.1 A rectal foam has also been developed, which may be easier to use, and retain in the bowel, than an enema.2 Budesonide is available as a modified-release oral dosage form for the management of active Crohn's disease. 1,3 Ileal-release preparations of budesonide have been indicated as first-line therapy in the treatment of mild to moderate ileal and right-sided colonic Crohn's disease.<sup>4</sup> Systematic review<sup>5</sup> has suggested that it is slightly less effective than conventional corticosteroid therapy, but is associated with fewer adverse effects. Budesonide has also been effective in delaying relapse in quiescent disease.<sup>6-8</sup> However, the benefit appears to be short-term (3 months)4 and it has been concluded that oral modified-release budesonide is not effective in long-term (12 months) maintenance of remission.<sup>4,9</sup> Similarly, oral budesonide was ineffective in preventing postoperative recurrence after resection for Crohn's disease.

For a discussion of inflammatory bowel disease, see p.1697.

- Spencer CM, McTavish D. Budesonide: a review of its pharma-cological properties and therapeutic efficacy in inflammatory bowel disease. *Drugs* 1995; 50: 854–72.
- Gross V, et al. Budesonide foam versus budesonide enema in active ulcerative proctitis and proctosigmoiditis. Aliment Phar-macol Ther 2006; 23: 303–12.
- 3. McKeage K, Goa KL. Budesonide (Entocort EC capsules): a review of its therapeutic use in the management of active Crohn's disease in adults. *Drugs* 2002; 62: 2263–82.
- 4. Lichtenstein GR, et al. American Gastroenterological Associa-Lichtenstein GR, et al. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. Gastroenterology 2006; 130: 935–9. Also available at: http://download.journals.elsevierhealth.com/pdfs/journals/0016-5085/PIIS0016508506000734.pdf (accessed 22/09/06)
   Seow CH, et al. Budesonide for induction of remission in Crohn's disease. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2008 (accessed 20/08/08)
- cessed 22/08/08).
- 6. Greenberg GR, et al. Oral budesonide as maintenance treatment for Crohn's disease: a placebo-controlled dose-ranging study. Gastroenterology 1996; 110: 45–51.

  7. Löfberg R, et al. Budesonide prolongs time to relapse in ileal
- and ileocaecal Crohn's disease: a placebo controlled one year study. Gut 1996; 39: 82-6.
- 8. Gross V, et al. Low dose oral pH modified release budesonide for maintenance of steroid induced remission in Crohn's disease. *Gut* 1998; **42:** 493–6.

  9. Simms L, Steinhart AH. Budesonide for maintenance of remis-
- Siminis L, Steffman AII. Bucksonder of Inflantendate of Ichinsision in Crohn's disease. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2001 (accessed 12/05/05).
- Hellers G, et al. Oral budesonide for prevention of postsurgical recurrence in Crohn's disease. Gastroenterology 1999; 116: 294–300.

## **Preparations**

Proprietary Preparations (details are given in Part 3)

Arg.: Aerovent; Airbude; Budefarma†; Budeson; Cuteral; Despex†; Entocort; Hypersol B; Inflammide; Infliplus; Kerpet†; Nastizol Hidrospray; Neumocort; Neumotex; Preetzonide; Pulmo Lisoflam; Rino-B; Spirocort: Austral.: Budamax; Entocort; Pulmicort; Rhinocort; Austria: Budian; Budosan; Entocort; Miflonide; Novolizer; Pulmicort; Rhinocort; Belg.: Budenofalk; Docbudeso, Entocort; Merckrhinobudesonide; Miflonide; Pulmicort; Rhinocort; **Braz.**: Budecort; Budiair; Busonid; Entocort; Millionide; Noex; Novopulmon†; Pulmicort; **Canad.**: Entocort; Pulmicort; Rhinocort; **Chile**: Aero-Bud; Aerovial; Budasmal; Budenofalk; Clebudan; Entocort†; Inflam Aero-Bud; Aerovai; Budasmar; Budenotais; Clebudar; Entocort; Initamide; Neumocort; Pulnicort; Rinicort; Cz.; Apulenir; Budenofalk; Budiair; Easi-Cort; Entocort; Giona; Inflammide; Miflonid; Pulmax, Pulmicort; Rhinocort; Ribuspir; Tafen; Tinkair; Denm.; Budenofalk; Entocort; Giona; Miflonide; Pulairmax; Rhinocort; Rhinosol; Spirocort; Fin.: Budenofalk; Cortivent; Entocort; Pulmicort; Rhinocort; Fir.: Entocort; Miflonik; Novopulmon; Pulmicort; Raflor; Rhinocort; Ger.: Aquacort; Benosid; Budapp; Budecort; Budefat; Budenofalk; Budes; Budiair; Budon; Entocort; Miflonik; Budiair; Budi

nide; Novopulmon; Pulmicort; Respicort†; **Gr.:** Arsicort; Astrocast; Aurid; Axelovert; Beysonit; Biosonide; Budecol; Budemar; Budenite; Budenofalk; Axelovert; Beysonit; Biosonide; Budecol; Budemar; Budenite; Budenofalik; Buderpro; Buderen; Budesan; Budesoderm; Budesonal; Budair; Busonal; Budair; Busonal; Butakont; Dedostryl; Dexalocal; Esonide; Etrafonil; Farlidone; Ixor; Lisobron; Lydenal†; Miflonide; Minalerg; Nalator; Obecirol; Obusonid; Olfosonide; Olysaj; Pimofalt; Pulmicort; Pulmiver; Pulmovance; Restat; Rhinobros; Rhinoside; Ribuspir; Rinoster; Serbo; Sonidal; Talgan; Therasound; Udesogel; Udesospray, Velorium; Vericort; Vinecort; Zefecort; Zymacter; Zyolalf; Zytual; Hong Kong: Budenase; Budenofalk; Cycortide; Entocort; Pulmicort; Hing.: Aerox; Apulein†; Budenofalk; Budesogen; Entocort; Miflonide; Neplit; Pulmax; Pulmicort; Riniocort; Indon.: Budenofalk; Inflammide; Pulmicort; Rhinocort; Indon.: Budenofalk; Inflammide; Pulmicort; Rhinocort; Indon.: Budenofalk; Ulmicort; Riniocort; Indon.: Budenofalk; Pulmicort; Riniocort; Indon.: Budenof cort; Nninocort; Mil.: Budenolaik; Entocort; Pulmicort; Nninocort; Israel: Budeson; Budicort; Entocort; Milfonide; Nasocort; Pulmotide; Tad.: Aircort; Bidien; Desonax; Eltair; Enterocir; Entocir; Kesol; Miflo; Miflonide; Preferid; Pulmaxarı; Rhinocort; Spirocort; Xavin; Malaysia: Budecort; Budenase; Budiair; Butacort; Eltair; Giona; Inflammide; Pulmicort; Rhinocort; Mex.: Aerosiai; Budosan; Entocort; Miflonide; Numark; Pulmicort; Rhinocort; Neth.: Budenofalk; Entocort; Pulmicort; Rhinocort; Norws: Entocort; Villagoret; Vil ort; Neth.: Budenolaik; Entocort; Fulmicort; Aninocort; Norw.: entocort; Giona; Pulmicort; Rhinocort; NZ: Butacort; Eltiar; Entocort; Pulmicort; Philipp.: Asmavent; Budecort; Budenofalk; Primavent; Pol.: Budenofalk; Buderhin; Entocort; Horacort; Miflonide; Neplit; Pulmicort; Rhinocort; Tafen; Port.: Aeromax; Budo-san; Entocort; Miflonide; Neo Rinactive; Pulнает, Port.: Aeromax; Budo-san; Entocort; Pillionide; Neo кластие; Pulmicort (Пульмикорт); Таfen (Тафен); S.Afr.: Budeflam; Entocord; Inflacor†; Inflammide; Inflamaze; Pulmicort; Rhinocort; Singapore: Budenofalk; Ettair; Entocort; Esonide; Giona; Inflammide; Pulmicort; Rhinocort; Spain: Budenofalk; Demotest; Entocord; Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Phinocort; Ribujet; Swed.: Budenofalk; Entocort; Circan Pulmicort; Phinocort; Suitar, Reference Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Phinocort; Suitar, Reference Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Phinocort; Suitar, Reference Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Phinocort; Suitar, Reference Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Suitar, Reference Millionide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Pulmic Prumicort; Pulmicort; Rhinocort; Switz: Budenofalk; Cortinasal; Entocort; Giona; Pulmicort; Rhinocort; Switz: Budenofalk; Cortinasal; Entocort; Miflonide; Pulmicort; Rhinocort; Thai.: Budecort; Bunase; Eltair; Giona; Inflammide†; Pulmicort; Rhinocort; Thai.: Budenofalk; Entocort; Inflacort; Wiflonid; Pulmicort; Rhinocort; USA: Entocort; Pulmicort; Rhinocort; USA: Entocort; Pulmicort; Rhinocort; USA: Entocort; Pulmicort; Pulmicort; Rhinocort; Rhino ort; Rinagua†; Rinolet.

Multi-ingredient: Arg.: Neumoterol; Symbicort; Austral.: Symbicort; Austria: Symbicort; Belg.: Symbicort; Braz.: Alenia; Foraseq; Symbicort; Canad.: Symbicort: Chile: Symbicort; Cz.: Symbicort; Denm.: Symbicort; Fin.: Symbicort; Gen.: Symbicort; Gr.: Symbicort; Hung.: Symbicort; India: Budesalt; Foracort; Indon.: Symbicort; India: Budesalt; Foracort; Indon.: Symbicort; India: Symbicort; Sinestic, Symbicort; Norw.: Symbicort; Mex.: Symbicort; Neth.: Assieme; Sinestic; Symbicort; Norw.: Віаstеп (Биастен); Simbicort (Симбикорт); **S.Afr.:** Symbicort; **Singapore:** Symbicort; **Spain:** Rilast; Symbicort; **Swed.:** Symbicort; **Switz.:** Symbicort; **Turk.**: Symbicort; **Turk.**: Symbicort; **UK:** Symbicort; **US:** Symbicort; **Venez.:** Foráseq; Symbicort.

## Ciclesonide (USAN, rINN) ⊗

BY-9010; Ciclesonida; Ciclésonide; Ciclesonidum; RPR-251526. (R)-11 $\beta$ , 16 $\alpha$ , 17,21-Tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with cyclohexanecarboxaldehyde, 21-isobutyrate.

Циклезонид

 $C_{32}H_{44}O_7 = 540.7.$ 

CAS - 126544-47-6; 141845-82-1.

ATC - RO3BA08.

ATC Vet - QR03BA08.

## Adverse Effects, Treatment, Withdrawal, and Precautions

As for corticosteroids in general (see p.1490).

Systemic absorption may follow inhalation of ciclesonide, particularly if high doses are used for prolonged periods.

### Interactions

The interactions of corticosteroids in general are described on p.1494.

### **Pharmacokinetics**

For a brief outline of the pharmacokinetics of corticosteroids, see p.1495. Ciclesonide is hydrolysed to its biologically active metabolite by esterase enzymes in the lung and nasal mucosa; the systemic bioavailability for the active metabolite is reported to be more than 50% when ciclesonide is given by metered-dose inhaler.