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 efficacy in asthma and rhinitis. *Drugs* 1992; **44:** 375–407 and 1012.
2. 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.
3. 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[3] 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[4] 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.

1. Carlsen KCL, *et al.* How much nebulised budesonide reaches infants and toddlers? *Arch Dis Child* 1992; **67:** 1077–9.
2. 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[1] of patients with primary biliary cirrhosis the clearance of oral budesonide 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.

1. Hempfling W, *et al.* Pharmacokinetics and pharmacodynamic action of budesonide in early- and late-stage primary biliary cirrhosis. *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]

1. 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.
3. 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.
4. 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; **59:** 550–6.
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 reviewed.[1]

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[1-5] 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 meta-analysis,[6] although high rates of relapse after stopping treatment have been reported.[3,5]

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 of 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 after induction of clinical remission with budesonide. *Aliment Pharmacol Ther* 2005; **22:** 1115–19.
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 study[1] 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[2] 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 hyperresponsiveness 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; **156:** 1190–6.

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.[4] Systematic review[5] 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.[6-8] 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.[4,9] Similarly, oral budesonide was ineffective in preventing postoperative recurrence after resection for Crohn's disease.[10]

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

1. Spencer CM, McTavish D. Budesonide: a review of its pharmacological properties and therapeutic efficacy in inflammatory bowel disease. *Drugs* 1995; **50:** 854–72.
2. Gross V, *et al.* Budesonide foam versus budesonide enema in active ulcerative proctitis and proctosigmoiditis. *Aliment Pharmacol 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 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)
5. 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 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 remission in Crohn's disease. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2001 (accessed 12/05/05).
10. 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; Proetzonide; Pulmo Lisoflam; Rino-B; Spirocort; ***Austral.:*** Budamax; Entocort; Pulmicort; Rhinocort; ***Austria:*** Budiair; Budosan; Entocort; Miflonide; Novolizer; Pulmicort; Rhinocort; ***Belg.:*** Budenofalk; Docbudeso; Entocort; Merckrhinobudesonide; Miflonide; Pulmicort; Rhinocort; ***Braz.:*** Budecort; Budiair; Busonid; Entocort; Miflonide; Noex; Novopulmon†; Pulmicort; ***Canad.:*** Entocort; Pulmicort; Rhinocort; ***Chile:*** Aero-Bud; Aerovial; Budasmal; Budenofalk; Clebudan; Entocort†; Inflammide; Neumocort; Pulmicort; Rhinocort; ***Cz.:*** Apulein†; 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; ***Fr.:*** Entocort; Miflonil; Novopulmon; Pulmicort; Rafton; Rhinocort; ***Ger.:*** Aquacort; Benosid†; Budapp†; Budecort; Budefat†; Budenofalk; Budes; Budiair; Budon†; Entocort; Miflonide; Novopulmon; Pulmicort; Respicort†; ***Gr.:*** Arsicort; Astrocast; Aurid; Axelovert; Beysonit; Biosonide; Budecol; Budemar; Budenite; Budenofalk; Budeprol; Buderen; Budesan; Budesoderm; Budesonal; Budiair; Busonal; Butekont; Dedostryl; Dexalocal; Esonide; Etrafonil; Farlidone; Ixor; Lisobron; Lydenal†; Miflonide; Minalerg; Nalator; Obecirol; Obusonid; Olfosonide; Olyspal; Pimoftal†; Pulmicort; Pulmiver; Pulmovance; Resata; Rhinobros; Rhinoside; Ribuspir; Rinoster; Serbo; Sonidal; Talgan; Therasound; Udesogel; Udesospray; Velorium; Vericort; Vinecort; Zefecort; Zymacter; Zyolaif; Zytual; ***Hong Kong:*** Budenase; Budenofalk; Cycortide; Entocort; Pulmicort; Rhinocort; ***Hung.:*** Aerox; Apulein†; Budenofalk; Budesogen; Entocort; Miflonide; Neplit; Pulmax; Pulmicort; Rhinocort; ***India:*** Budecort†; Budenase†; Pulmicort; Rhinocort; ***Indon.:*** Budenofalk; Inflammide; Pulmicort; Rhinocort; ***Irl.:*** Budenofalk; Entocort; Pulmicort; Rhinocort; ***Israel:*** Budeson; Budicort; Entocort; Miflonide; Nasocort; Pulmotide†; ***Ital.:*** Aircort; Bidien; Desonax; Eltair; Enterocir†; Entocir; Kesol; Miflo; Miflonide; Preferid; Pulmaxan; Rhinocort; Spirocort; Xavin; ***Malaysia:*** Budecort; Budenase; Budiair; Butacort; Eltair; Giona; Inflammide; Pulmicort; Rhinocort; ***Mex.:*** Aerosial; Budosan; Entocort; Miflonide; Numark; Pulmicort; Rhinocort; ***Neth.:*** Budenofalk; Entocort; Pulmicort; Rhinocort; ***Norw.:*** Entocort; Giona; Pulmicort; Rhinocort; ***NZ:*** Butacort; Eltair; 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; Pulmax; Pulmicort; ***Rus.:*** Benacort (Бенакорт); Benarin (Бенарин); Pulmicort (Пульмикорт); Tafen (Тафен); ***S.Afr.:*** Budeflam; Entocord; Inflacor†; Inflammide; Inflanaze; Pulmicort; Rhinocort; ***Singapore:*** Budenofalk; Eltair; Entocort†; Esonide; Giona; Inflammide; Pulmicort; Rhinocort; ***Spain:*** Budenofalk; Demotest; Entocord; Miflonide; Neo Rinactive; Novopulm; Olfex; Pulmicort; Pulmictan; Rhinocort; Ribujet; ***Swed.:*** Budenofalk; Entocort; Giona; Pulmicort; Rhinocort; ***Switz.:*** Budenofalk; Cortinasal; Entocort; Miflonide; Pulmicort; Rhinocort; ***Thai.:*** Budecort; Bunase; Eltair; Giona; Inflammide†; Pulmicort; Rhinocort; ***Turk.:*** Budenofalk; Entocort; Inflacort; Miflonid; Pulmicort; Rhinocort; ***UAE:*** Sonidar; ***UK:*** Budenofalk; Entocort; Pulmicort; Rhinocort; ***USA:*** Entocort; Pulmicort; Rhinocort; ***Venez.:*** Biosonida; Bronklast; Budecort; Budenas; Miflonide; Pulmicort; Pulmolet; Rhinocort; Rinaqua†; 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; ***Fr.:*** Symbicort; ***Ger.:*** Symbicort; ***Gr.:*** Symbicort; ***Hong Kong:*** Symbicort; ***Hung.:*** Symbicort; ***India:*** Budesal†; Foracort; ***Indon.:*** Symbicort; ***Irl.:*** Symbicort; ***Israel:*** Symbicort; ***Ital.:*** Assieme; Sinestic; Symbicort; ***Malaysia:*** Foracort; Symbicort; ***Mex.:*** Symbicort; ***Neth.:*** Assieme; Sinestic; Symbicort; ***Norw.:*** Symbicort; ***NZ:*** Symbicort; ***Philipp.:*** Symbicort; ***Pol.:*** Symbicort; ***Port.:*** Assieme; Symbicort; ***Rus.:*** Biasten (Биастен); Simbicort (Симбикорт); ***S.Afr.:*** Symbicord; ***Singapore:*** Symbicort; ***Spain:*** Rilast; Symbicort; ***Swed.:*** Symbicort; ***Switz.:*** Symbicort; ***Thai.:*** Symbicort; ***Turk.:*** Symbicort; ***UK:*** Symbicort; ***USA:*** Symbicort; ***Venez.:*** Foraseq; Symbicort.

Ciclesonide *(USAN, rINN)* ⊗

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

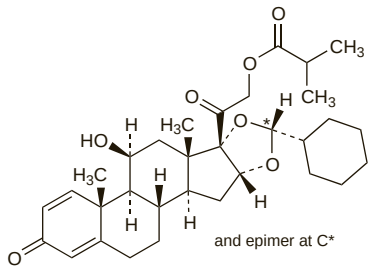
Циклезонид

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

CAS — 126544-47-6; 141845-82-1.

ATC — R03BA08.

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.

Oral bioavailability is less than 1%. Ciclesonide and its active metabolite are extensively bound to plasma proteins. It is further metabolised to inactive metabolites via the cytochrome P450 isoenzyme CYP3A4. After oral or intravenous dosage, ciclesonide is mainly excreted via the faeces.

◊ References.

1. Rohatagi S, *et al.* Population pharmacokinetics and pharmacodynamics of ciclesonide. *J Clin Pharmacol* 2003; **43:** 365–78.
2. Nave R, *et al.* Pharmacokinetics of [C]ciclesonide after oral and intravenous administration to healthy subjects. *Clin Pharmacokinet* 2004; **43:** 479–86.
3. Derendorf H. Pharmacokinetic and pharmacodynamic properties of inhaled ciclesonide. *J Clin Pharmacol* 2007; **47:** 782–9.

Uses and Administration

Ciclesonide is a corticosteroid with glucocorticoid activity (p.1490). It is used by inhalation in the management of asthma (p.1108) in adults and adolescents aged 12 years and older. The usual dose is 160 micrograms once daily from a metered-dose aerosol; the dose may be reduced to 80 micrograms once daily for maintenance. It is preferably given in the evening. Ciclesonide is given intranasally for the treatment of seasonal and perennial allergic rhinitis (p.565) in adults and adolescents 12 years of age and older; children 6 years of age and older may be treated for seasonal allergic rhinitis. A dose of 200 micrograms once daily is given as 2 sprays of 50 micrograms into each nostril.

◊ References.

1. Postma DS, *et al.* Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening. *Eur Respir J* 2001; **17:** 1083–8.
2. Reynolds NA, Scott LJ. Ciclesonide. *Drugs* 2004; **64:** 511–19.
3. Christie P. Ciclesonide: a novel inhaled corticosteroid for asthma. *Drugs Today* 2004; **40:** 569–76.
4. Chapman KR, *et al.* Maintenance of asthma control by once-daily inhaled ciclesonide in adults with persistent asthma. *Allergy* 2005; **60:** 330–7.
5. Dhillon S, Wagstaff AJ. Ciclesonide nasal spray: in allergic rhinitis. *Drugs* 2008; **68:** 875–83.

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Alvesco; Cicletex; ***Austral.:*** Alvesco; ***Braz.:*** Alvesco; ***Chile:*** Alvesco; ***Cz.:*** Alvesco; ***Gr.:*** Alvesco; Amavio; Freathe; ***Hong Kong:*** Alvesco; ***Hung.:*** Alvesco; ***India:*** Osonide; ***Irl.:*** Alvesco; ***Malaysia:*** Alvesco; ***Mex.:*** Alvesco; ***Neth.:*** Alvesco; ***Pol.:*** Alvesco; ***S.Afr.:*** Alvesco; ***UK:*** Alvesco; ***USA:*** Alvesco; Omnaris; ***Venez.:*** Alvesco.

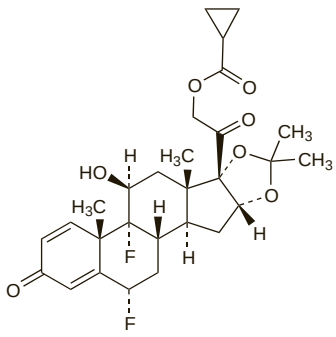
Ciprocinonide *(USAN, rINN)* ⊗

Ciprocinonida; Ciprocinonidum; RS-2386. (6α,11β,16α)-21-[(cyclopropylcarbonyl)oxy]-6,9-difluoro-11-hydroxy-16,17-[(1-methylethylidene)-bis(oxy)]-pregna-1,4-diene-3,20-dione.

Ципроцинонид

$C_{28}H_{34}F_2O_7$ = 520.6.

CAS — 58524-83-7.



Profile

Ciprocinonide is a derivative of fluocinolone acetonide (p.1531) that has been applied topically with fluocinonide and procinonide in the management of various skin disorders.

Clobetasol Propionate *(BANM, USAN, rINNM)* ⊗

CCI-4725; Clobétasol, propionate de; Clobetasoli propionas; GR-2/925; Klobetasol-propionát; Klobetazol Propiyonat; Klobetazolu propionian; Propionato de clobetasol. 21-Chloro-9α-fluoro-11β,17α-dihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-propionate.

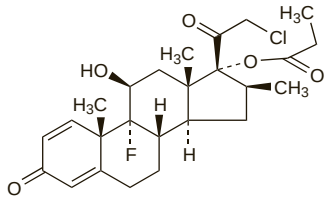
Клобетазола Пропионат

$C_{25}H_{32}ClFO_5$ = 467.0.

CAS — 25122-41-2 (clobetasol); 25122-46-7 (clobetasol propionate).

ATC — D07AD01.

ATC Vet — QD07AD01.



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

Ph. Eur. 6.2 (Clobetasol Propionate). A white or almost white, crystalline powder. Practically insoluble in water; sparingly soluble in alcohol; freely soluble in acetone. Protect from light.

USP 31 (Clobetasol Propionate). A white to cream crystalline powder. Practically insoluble in water; sparingly soluble in dehydrated alcohol; soluble in acetone, in chloroform, in dimethyl sulfoxide, in dioxan, and in methyl alcohol; slightly soluble in benzene and in ether. Store in airtight containers. Protect from light.

Profile

Clobetasol propionate is a corticosteroid used topically for its glucocorticoid activity (p.1490) in the treatment of various skin disorders. It is usually used as a cream, ointment, gel, scalp application, or foam containing 0.05%.

When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects (p.1490). The effects of topical corticosteroids on the skin are described on p.1492. 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.

◊ References.

1. Campisi G, *et al.* A new delivery system of clobetasol-17-propionate (lipid-loaded microspheres 0.025%) compared with a conventional formulation (lipophilic ointment in a hydrophilic phase 0.025%) in topical treatment of atrophic/erosive oral lichen planus: a phase IV, randomized, observer-blinded, parallel group clinical trial. *Br J Dermatol* 2004; **150:** 984–90.
2. Jarratt M, *et al.* Clobetasol propionate shampoo 0.05%: a new option to treat patients with moderate to severe scalp psoriasis. *J Drugs Dermatol* 2004; **3:** 367–73.
3. Reygagne P, *et al.* Clobetasol propionate shampoo 0.05% and calcipotriol solution 0.005%: a randomized comparison of efficacy and safety in subjects with scalp psoriasis. *J Dermatol Treat* 2005; **16:** 31–6.
4. Breneman D, *et al.* Clobetasol propionate 0.05% lotion in the treatment of moderate to severe atopic dermatitis: a randomized evaluation versus clobetasol propionate emollient cream. *J Drugs Dermatol* 2005; **4:** 330–6.
5. Lowe N, *et al.* Clobetasol propionate lotion, an efficient and safe alternative to clobetasol propionate emollient cream in subjects with moderate to severe plaque-type psoriasis. *J Dermatol Treat* 2005; **16:** 158–64.
6. Reid DC, Kimball AB. Clobetasol propionate foam in the treatment of psoriasis. *Expert Opin Pharmacother* 2005; **6:** 1735–40.
7. Sanchez Regana M, *et al.* Treatment of nail psoriasis with 8% clobetasol nail lacquer: positive experience in 10 patients. *J Eur Acad Dermatol Venereol* 2005; **19:** 573–7.
8. Conrotto D, *et al.* Ciclosporin vs. clobetasol in the topical management of atrophic and erosive oral lichen planus: a double-blind, randomized controlled trial. *Br J Dermatol* 2006; **154:** 139–45.
9. Vena GA, *et al.* Clobetasol propionate 0.05% in a novel foam formulation is safe and effective in the short-term treatment of patients with delayed pressure urticaria: a randomized, double-blind, placebo-controlled trial. *Br J Dermatol* 2006; **154:** 353–6.

Preparations

BP 2008: Clobetasol Cream; Clobetasol Ointment;
USP 31: Clobetasol Propionate Cream; Clobetasol Propionate Ointment; Clobetasol Propionate Topical Solution.

Proprietary Preparations (details are given in Part 3)

Arg.: Cantril†; Clobesol; Clobex; Dermaclob; Dermadex; Dermexane; Perfracort; Ribatra; Salac; ***Austria:*** Dermovate; ***Belg.:*** Dermovate; ***Braz.:*** Clob-X; Clobesol; Cortalen C; Dermacare; Propiosol; Psorex; Psorin; Therapsor; ***Canad.:*** Clobex; Dermasone†; Dermovate; ***Chile:*** Alticort; Clob-X; Clodavan; Cortopic; Dermovate; Koniderm; Lobevat†; Xinder; ***Cz.:*** Clobex; Dermovate; ***Denm.:*** Dermovat; ***Fin.:*** Dermovat; ***Fr.:*** Dermoval; ***Ger.:*** Clobegalen; Dermoxin; Dermoxinale; Karison; ***Gr.:*** Butavate; Clarelux; Rubocort; ***Hong Kong:*** Clobasol; Clobesol; Clobex; Dermasone†; Dermo; Dermovate; Dhabesol; Eurobetsol; Medodermone; Uniderm; ***Hung.:*** Closanasol; Dermovate; ***India:*** Cloderm; Lobate; Tenovate; Topifort; ***Indon.:*** Bersol; Closol; Dermovate; Elopro; Forderm; Ikaderm; Kloderma; Klonat; Lamodex; Lotasbat; Primaderm; Psoriderm; ***Irl.:*** Dermovate; ***Israel:*** Dermovate; ***Ital.:*** Clobesol; ***Malaysia:*** Betasol†; Clobet; Cloderm; Dermapro†; Dermosol; Dermovate; Dhabesol; Lobesol†; Uniderm; Univate†; ***Mex.:*** Clobesol; Dermatovate; Lobevat; ***Neth.:*** Clarelux; Clobex; Dermovate; Olux†; ***Norw.:*** Dermovat; ***NZ:*** Dermol; ***Philipp.:*** Clonate; Closderm; Dermovate; Glevate; ***Pol.:*** Clobederm; Dermklobal; Dermovate; Novate; ***Port.:*** Clarelux; Dermovate; Etrivex; ***Rus.:*** Dermovate (Дермовейт); ***S.Afr.:*** Dermovate; Dovate; Xenovate; ***Singapore:*** Clobeson†; Cloderm; Dermosol; Dermovate; Dhabesol; Medodermone; Powercort; Uniderm; Univate; ***Spain:*** Clovate; Decloban; ***Swed.:*** Dermovat; ***Switz.:*** Dermovate; ***Thai.:*** Betasol; Clinoderm; Clobasone; Clobet; Clobetate; Cloderm; Clonovate; Cotaso; Dermasil†; Dermovate; Mededermone†; P-Vate; Stivate; Uniderm; ***Turk.:*** Dermovate; Psoderm; Psovate; ***UAE:*** Gamavate; ***UK:*** Clarelux; Dermovate; Etrivex; ***USA:*** Clobex; Cormax; Embeline†; Olux; Temovate; ***Venez.:*** Dermovate.

Multi-ingredient: ***Arg.:*** Clobeplus; Clobesol LA; Dermadex NN; ***India:*** Cloderm GM; Lobate-G; Lobate-GM; Lobate-M; Tenovate G; Tenovate M; ***Philipp.:*** Dermovate-NN; ***Port.:*** Dermovate-NN†; ***Switz.:*** Dermovate-NN; ***UK:*** Dermovate-NN.

Clobetasone Butyrate *(BANM, USAN, rINNM)* ⊗

Butirato de clobetasona; CCI-5537; Clobétasone, butyrate de; Clobetasoni Butiras; Clobetasoni butyras; GR-2/1214; Klobetasonbutyrat; Klobetason-butyrát; Klobetasonibutyraatti; Klobetazon Bütirat; Klobetazon-butirát; Klobetazono butiratas. 21-Chloro-9α-fluoro-17α-hydroxy-16β-methylpregna-1,4-diene-3,11,20-trione 17-butyrate.

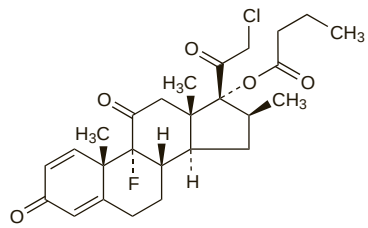
Клобетазона Бутират

$C_{26}H_{32}ClFO_5$ = 479.0.

CAS — 54063-32-0 (clobetasone); 25122-57-0 (clobetasone butyrate).

ATC — D07AB01; S01BA09.

ATC Vet — QD07AB01; QS01BA09.



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

Ph. Eur. 6.2 (Clobetasone Butyrate). A white or almost white powder. Practically insoluble in water; slightly soluble in alcohol; freely soluble in acetone and in dichloromethane. Protect from light.

Profile

Clobetasone butyrate is a corticosteroid used topically for its glucocorticoid activity (p.1490) in the treatment of various skin disorders. It is usually used as a cream or ointment containing 0.05%. When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects (p.1490). The effects of topical corticosteroids on the skin are described on p.1492. 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.

Clobetasone butyrate is also used for inflammatory eye disorders, as eye drops containing 0.1%. Prolonged use of ophthalmic preparations containing corticosteroids has caused raised intraocular pressure and reduced visual function.

Preparations

BP 2008: Clobetasone Cream; Clobetasone Ointment.

Proprietary Preparations (details are given in Part 3)

Arg.: Eumovate; ***Austria:*** Emovate; ***Belg.:*** Eumovate; ***Braz.:*** Eumovate; ***Canad.:*** Eumovate; ***Chile:*** Eumovate†; ***Denm.:*** Emovat; ***Fin.:*** Emovat; ***Ger.:*** Emovate; ***Gr.:*** Rettavate; ***Hong Kong:*** Eumovate; ***India:*** Eumosone; ***Irl.:*** Eumovate; ***Israel:*** Eumovate; ***Ital.:*** Clobet; Eumovate; Visucloben; ***Malaysia:*** Cortoftal†; Eumovate; Euvaderm†; U-Closone; ***Neth.:*** Eumovate; ***Norw.:*** Cloptison†; ***NZ:*** Eumovate; ***Port.:*** Emovate; ***S.Afr.:*** Eumovate; ***Singapore:*** Amisol; Eumovate; ***Spain:*** Cortoftal†; Emovate; ***Swed.:*** Emovat; ***Switz.:*** Emovate; ***Thai.:*** Eumovate†; ***Turk.:*** Eumovate; ***UK:*** Eumovate; ***Venez.:*** Eumovate.

Multi-ingredient: ***Arg.:*** Cloptison-N†; ***India:*** Eumosone-G; Eumosone-M; ***Israel:*** Cicloderm-C; ***Ital.:*** Visucloben Antibiotico; Visucloben Decongestionante; ***UK:*** Trimovate.