Dexamethasone *(BAN, rINN)* ⊗

Deksametasoni; Deksametazon; Deksametazonas; Desamethasone; Dexametason; Dexametasona; Dexametasone; Dexametazon; Dexamethason; Dexaméthasone; Dexamethasonum; 9α-Fluoro-16α-methylprednisolone; Hexadecadrol. 9α-Fluoro-11β,17α,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione.

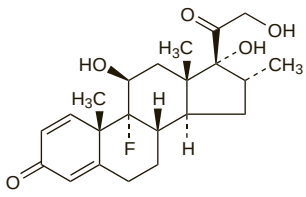
Дексаметазон

$C_{22}H_{29}FO_5$ = 392.5.

CAS — 50-02-2.

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QD07XB05; QD10AA03; QH02AB02; QR01AD03; QS01BA01; QS01CB01; QS02BA06; QS03BA01.



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

Ph. Eur. 6.2 (Dexamethasone). A white or almost white, crystalline powder. Practically insoluble in water; sparingly soluble in dehydrated alcohol; slightly soluble in dichloromethane. Protect from light.

USP 31 (Dexamethasone). A white to practically white, odourless, crystalline powder. Practically insoluble in water; sparingly soluble in alcohol, in acetone, in dioxan, and in methyl alcohol; slightly soluble in chloroform; very slightly soluble in ether.

Dexamethasone Acetate *(BANM, USAN, rINNM)* ⊗

Acetato de dexametasona; Deksametasoniasetaatti; Deksametazono acetatas; Dexametasonacetat; Dexametazon-acetát; Dexamethason-acetát; Dexaméthasone, acétate de; Dexamethasoni acetas. Dexamethasone 21-acetate.

Дексаметазона Ацетат

$C_{24}H_{31}FO_6$ = 434.5.

CAS — 1177-87-3 (anhydrous dexamethasone acetate); 55812-90-3 (dexamethasone acetate monohydrate).

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QH02AB02; QR01AD03; QS01BA01; QS02BA06; QS03BA01.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *Viet.*
Int. and *US* allow the anhydrous form or the monohydrate.

Ph. Eur. 6.2 (Dexamethasone Acetate). A white or almost white, crystalline powder. It shows polymorphism. Practically insoluble in water; freely soluble in alcohol and in acetone; slightly soluble in dichloromethane. Protect from light.

USP 31 (Dexamethasone Acetate). It contains one molecule of water of hydration or is anhydrous. A clear, white to off-white, odourless powder. Practically insoluble in water; freely soluble in acetone, in dioxan, and in methyl alcohol. Store at a temperature of 25°, excursions permitted between 15° and 30°.

Dexamethasone Isonicotinate *(BANM, rINNM)* ⊗

Deksametasoniisonikotinaatti; Deksametazonu izonikotynian; Dexametasonisonikotinat; Dexaméthasone, isonicotinate de; Dexamethasoni isonicotinas; Dexamethason-isonikotinát; Isonicotinato de dexametasona. Dexamethasone 21-isonicotinate.

Дексаметазона Изоникотинат

$C_{28}H_{32}FNO_6$ = 497.6.

CAS — 2265-64-7.

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QH02AB02; QR01AD03; QS01BA01; QS02BA06; QS03BA01.

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

Ph. Eur. 6.2 (Dexamethasone Isonicotinate). A white or almost white crystalline powder. Practically insoluble in water; slightly soluble in dehydrated alcohol and in acetone.

Dexamethasone Phosphate *(BANM, rINNM)* ⊗

Dexaméthasone, Phosphate de; Dexamethasoni Phosphas; Fosfato de dexametasona. Dexamethasone 21-(dihydrogen phosphate).

Дексаметазона Фосфат

$C_{22}H_{30}FO_8P$ = 472.4.

CAS — 312-93-6.

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QH02AB02; QR01AD03; QS01BA01; QS02BA06; QS03BA01.

Dexamethasone Sodium Metasulfobenzoate *(rINNM)* ⊗

Dexaméthasone Métasulfobenzoate Sodique; Dexamethasone Sodium Metasulphobenzoate *(BANM)*; Metasulfobenzoato sódico de dexametasona; Natrii Dexamethasoni Metasulfobenzoas. Dexamethasone 21-(sodium *m*-sulphobenzoate).

Натрий Метасульфобензоат Дексаметазон

$C_{29}H_{32}FNaO_9S$ = 598.6.

CAS — 3936-02-5.

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QH02AB02; QR01AD03; QS01BA01; QS02BA06; QS03BA01.

Dexamethasone Sodium Phosphate

(BANM, rINNM) ⊗

Deksametasoninatriumfosfaatti; Deksametazon Sodyum Fosfat; Deksametazono natrio fosfatas; Dexametasonnatriumfosfat; Dexametazon-nátrium-foszfát; Dexaméthasone, phosphate sodique de; Dexamethasone Phosphate Sodium; Dexamethason-fosfát sodná sůl; Dexamethasoni natrii phosphas; Fosfato sódico de dexametasona; Natrii Dexamethasoni Phosphas; Sodium Dexamethasone Phosphate. Dexamethasone 21-(disodium orthophosphate).

Натрия Дексаметазона Фосфат

$C_{22}H_{28}FNa_2O_8P$ = 516.4.

CAS — 2392-39-4.

ATC — A01AC02; C05AA09; D07AB19; H02AB02; R01AD03; S01BA01; S02BA06; S03BA01.

ATC Vet — QA01AC02; QC05AA09; QD07AB19; QH02AB02; QR01AD03; QS01BA01; QS02BA06; QS03BA01.

NOTE. DSP is a code approved by the BP 2008 for use on single unit doses of eye drops containing dexamethasone sodium phosphate where the individual container may be too small to bear all the appropriate labelling information.

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

Ph. Eur. 6.2 (Dexamethasone Sodium Phosphate). A white or almost white, very hygroscopic, powder. It exhibits polymorphism. Freely soluble in water; slightly soluble in alcohol; practically insoluble in dichloromethane. A 1% solution in water has a pH of 7.5 to 9.5. Store in airtight containers. Protect from light.

USP 31 (Dexamethasone Sodium Phosphate). A white or slightly yellow, crystalline powder. Is odourless or has a slight odour of alcohol, and is exceedingly hygroscopic. Soluble 1 in 2 of water; slightly soluble in alcohol; insoluble in chloroform and in ether; very slightly soluble in dioxan. pH of a 1% solution in water is between 7.5 and 10.5. Store in airtight containers.

Adverse Effects, Treatment, Withdrawal, and Precautions

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

Dexamethasone has little or no effect on sodium and water retention.

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. Prolonged use of ophthalmic preparations containing corticosteroids has caused raised intra-ocular pressure and reduced visual function.

Effects on the neonate. The adverse effects of corticosteroids on the fetus are discussed under Pregnancy on p.1494.

Adverse effects noted in premature neonates with bronchopulmonary dysplasia (p.1500) receiving dexamethasone treatment to enable weaning from assisted ventilation have included hypertension[1-4] often accompanied by bradycardia,[1,2] gastroduodenal perforation,[4-6] ulceration and thinning of the gastric wall,[5] development of a catabolic state,[4,7] renal calcification,[8,9] and transient myocardial hypertrophy.[10-13] There is some evidence of a suppressive effect on motor activity and spontaneous movement.[14] It has been postulated that neonatal dexamethasone may both increase[15] and decrease[16] retinopathy of prematurity; its true effect is uncertain.[17]

There is also a concern that longer term development of the child may be adversely affected.[18,19] Although data are scanty, a meta-analysis[20] has concluded that postnatal use of corticosteroids to treat or prevent bronchopulmonary dysplasia is associated with dramatic increases in the incidence of cerebral palsy and neurodevelopmental impairment, and suggested that such use should be abandoned.

Pulsed dosage may reduce the adverse effects but may also reduce efficacy.[21]

1. Ohlsson A, Heyman E. Dexamethasone-induced bradycardia. *Lancet* 1988; **ii:** 1074.
2. Puntis JWL, *et al.* Dexamethasone-induced bradycardia. *Lancet* 1988; **ii:** 1372.
3. Marinelli KA, *et al.* Effects of dexamethasone on blood pressure in premature infants with bronchopulmonary dysplasia. *J Pediatr* 1997; **130:** 594–602.
4. Stark AR, *et al.* Adverse effects of early dexamethasone treatment in extremely-low-birth-weight infants. *N Engl J Med* 2001; **344:** 95–101.
5. Ng PC, *et al.* Gastroduodenal perforation in preterm babies treated with dexamethasone for bronchopulmonary dysplasia. *Arch Dis Child* 1991; **66:** 1164–6.
6. Smith H, Sinha S. Gastrointestinal complications associated with dexamethasone treatment. *Arch Dis Child* 1992; **67:** 667.
7. Macdonald PD, *et al.* A catabolic state in dexamethasone treatment of bronchopulmonary dysplasia. *Arch Dis Child* 1990; **65:** 560–1.
8. Kamitsuka MD, Peloquin D. Renal calcification after dexamethasone in infants with bronchopulmonary dysplasia. *Lancet* 1991; **337:** 626.
9. Narendra A, *et al.* Nephrocalcinosis in preterm babies. *Arch Dis Child Fetal Neonatal Ed* 2001; **85:** F207–F213.
10. Werner JC, *et al.* Hypertrophic cardiomyopathy associated with dexamethasone therapy for bronchopulmonary dysplasia. *J Pediatr* 1992; **120:** 286–91.
11. Bensky AS, *et al.* Cardiac effects of dexamethasone in very low birth weight infants. *Pediatrics* 1996; **97:** 818–21.
12. Skelton R, *et al.* Cardiac effects of short course dexamethasone in preterm infants. *Arch Dis Child* 1998; **78:** F133–F137.
13. Zecca E, *et al.* Cardiac adverse effects of early dexamethasone treatment in preterm infants: a randomized clinical trial. *J Clin Pharmacol* 2001; **41:** 1075–81.
14. Bos AF, *et al.* Qualitative assessment of general movements in high-risk preterm infants with chronic lung-disease requiring dexamethasone therapy. *J Pediatr* 1998; **132:** 300–6.
15. Batton DG, *et al.* Severe retinopathy of prematurity and steroid exposure. *Pediatrics* 1992; **90:** 534–6.
16. Sobel DB, Philip AGS. Prolonged dexamethasone therapy reduces the incidence of cryotherapy for retinopathy of prematurity in infants of less than 1 kilogram birth weight with bronchopulmonary dysplasia. *Pediatrics* 1992; **90:** 529–33.
17. Ehrenkranz RA. Steroids, chronic lung disease, and retinopathy of prematurity. *Pediatrics* 1992; **90:** 646–7.
18. Greenough A. Gains and losses from dexamethasone for neonatal chronic lung disease. *Lancet* 1998; **352:** 835–6.
19. Shinwell ES, *et al.* Early postnatal dexamethasone treatment and increased incidence of cerebral palsy. *Arch Dis Child Fetal Neonatal Ed* 2000; **83:** F177–F181.
20. Barrington KJ. The adverse neuro-developmental effects of postnatal steroids in the preterm infant: a systematic review of RCTs. *BMC Pediatr* 2001; **1:** 1. Available at: http://www.biomedcentral.com/1471-2431/1/1 (accessed 27/04/04)
21. Bloomfield FH, *et al.* Side effects of 2 different dexamethasone courses for preterm infants at risk of chronic lung disease: a randomized trial. *J Pediatr* 1998; **133:** 395–400.

Effects on the nervous system. Paraesthesia, usually localised to the perineum, has been associated with the intravenous use of dexamethasone sodium phosphate (see p.1492).

Interactions

The interactions of corticosteroids in general are described on p.1494. Various drugs may interfere with the dexamethasone suppression test.

Antiepileptics. As mentioned on p.499, dexamethasone may decrease or increase plasma concentrations of *phenytoin*. Like other enzyme-inducing drugs, phenytoin also has the potential to increase the metabolism of dexamethasone. There have been reports of false positive dexamethasone suppression tests (see Diagnosis and Testing, below) in patients taking *carbamazepine*.[1]

1. Ma RCW, *et al.* Carbamazepine and false positive dexamethasone suppression tests for Cushing's syndrome. *BMJ* 2005; **330:** 299–300.

Pharmacokinetics

For a brief outline of the pharmacokinetics of corticosteroids, see p.1495.

Dexamethasone is readily absorbed from the gastrointestinal tract. Its biological half-life in plasma is about 190 minutes. Binding of dexamethasone to plasma proteins is about 77%, which is less than for most other corticosteroids. Up to 65% of a dose is excreted in urine within 24 hours. Clearance in premature neonates is reported to be proportional to gestational age, with a reduced elimination rate in the most premature. It readily crosses the placenta with minimal inactivation.

Uses and Administration

Dexamethasone is a corticosteroid with mainly glucocorticoid activity (p.1490); 750 micrograms of dexa-