3. Barrett-Connor E, *et al.* Effects of raloxifene on cardiovascular events and breast cancer in postmenopausal women. *N Engl J Med* 2006; **355:** 125–37.
4. Lippman ME, *et al.* Effect of raloxifene on the incidence of invasive breast cancer in postmenopausal women with osteoporosis categorized by breast cancer risk. *Clin Cancer Res* 2006; **12:** 5242–7.
5. Vogel VG, *et al.* Effects of tamoxifen vs raloxifene on the risk of developing invasive breast cancer and other disease outcomes: the NSABP Study of Tamoxifen and Raloxifene (STAR) P-2 trial. *JAMA* 2006; **295:** 2727–41. Corrections. *ibid.*; **296:** 2926 and *ibid.* 2007; **298:** 973.

Osteoporosis. Raloxifene partially mimics the effects of oestrogens in bone to increase bone mineral density in postmenopausal women.[1,2] The MORE study in 7705 postmenopausal women with osteoporosis (p.1084) found that up to 4 years of raloxifene treatment reduced the risk of vertebral fracture,[3-6] but the risk of nonvertebral fracture did not differ significantly from that in women given placebo.[3,5] A meta-analysis[7] of data from this and other smaller studies concluded that raloxifene reduced the risk of vertebral fracture by between 40 and 49% in postmenopausal women with osteoporosis.

Small studies suggest that raloxifene may be effective as 'add-back' therapy to prevent the loss of bone mineral density associated with gonadorelin analogue therapy in women[8,9] and men.[10]

1. Clemett D, Spencer CM. Raloxifene: a review of its use in postmenopausal osteoporosis. *Drugs* 2000; **60:** 379–411.
2. Cranney A, Adachi JD. Benefit-risk assessment of raloxifene in postmenopausal osteoporosis. *Drug Safety* 2005; **28:** 721–30.
3. Ettinger B, *et al.* Multiple Outcomes of Raloxifene Evaluation Investigators. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. *JAMA* 1999; **282:** 637–45.
4. Maricic M, *et al.* Early effects of raloxifene on clinical vertebral fractures at 12 months in postmenopausal women with osteoporosis. *Arch Intern Med* 2002; **162:** 1140–3.
5. Delmas PD, *et al.* Multiple Outcomes of Raloxifene Evaluation Investigators. Efficacy of raloxifene on vertebral fracture risk reduction in postmenopausal women with osteoporosis: four-year results from a randomized clinical trial. *J Clin Endocrinol Metab* 2002; **87:** 3609–17.
6. Qu Y, *et al.* The effect of raloxifene therapy on the risk of new clinical vertebral fractures at three and six months: a secondary analysis of the MORE trial. *Curr Med Res Opin* 2005; **21:** 1955–9.
7. Seeman E, *et al.* Anti-vertebral fracture efficacy of raloxifene: a meta-analysis. *Osteoporos Int* 2006; **17:** 313–16.
8. Palomba S, *et al.* Raloxifene administration in women treated with gonadotropin-releasing hormone agonist for uterine leiomyomas: effects on bone metabolism. *J Clin Endocrinol Metab* 2002; **87:** 4476–81.
9. Palomba S, *et al.* Long-term effectiveness and safety of GnRH agonist plus raloxifene administration in women with uterine leiomyomas. *Hum Reprod* 2004; **19:** 1308–14.
10. Smith MR, *et al.* Raloxifene to prevent gonadotropin-releasing hormone agonist-induced bone loss in men with prostate cancer: a randomized controlled trial. *J Clin Endocrinol Metab* 2004; **89:** 3841–6.

Preparations

USP 31: Raloxifene Hydrochloride Tablets.

Proprietary Preparations (details are given in Part 3)
Arg.: Biofem†; Ciclotran†; Evista; Ketidin; Loxifen†; Oseofem; Raxeto; ***Austral.:*** Evista; ***Austria:*** Evista; ***Belg.:*** Evista; ***Braz.:*** Evista; ***Canad.:*** Evista; ***Chile:*** Evista; ***Cz.:*** Evista; Optruma; ***Denm.:*** Evista; ***Fin.:*** Evista; Optruma†; ***Fr.:*** Evista; Optruma; ***Ger.:*** Evista; Optruma; ***Gr.:*** Evista; ***Hong Kong:*** Evista; ***Hung.:*** Evista; ***India:*** Bonmax; Estroact; Ralista; ***Indon.:*** Evista; ***Irl.:*** Evista; ***Israel:*** Evista; ***Ital.:*** Evista; Optruma; ***Jpn:*** Evista; ***Malaysia:*** Evista; ***Mex.:*** Evista; ***Neth.:*** Evista; Optruma; ***Norw.:*** Evista; ***NZ:*** Evista; ***Philipp.:*** Evista; ***Pol.:*** Evista; ***Port.:*** Evista; Optruma; ***S.Afr.:*** Evista; ***Singapore:*** Evista; ***Spain:*** Evista; Optruma; ***Swed.:*** Evista; ***Switz.:*** Evista; ***Thai.:*** Celvista; ***Turk.:*** Evista; ***UK:*** Evista; ***USA:*** Evista; ***Venez.:*** Evista.

Stanozolol *(BAN, USAN, rINN)* ⊗

Androstanazol; Androstanazole; Estanazol; Estanozolol; Methylstanazole; Metistanazol; NSC-43193; Stanotsololi; Stanozololis; Stanozololum; Stanozolum; Sztanozolol; Win-14833. 17α-Methyl-2′*H*-5α-androst-2-eno[3,2-*c*]pyrazol-17β-ol.

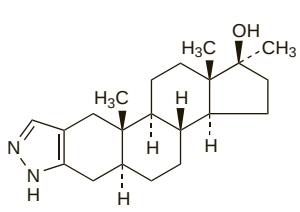
Станозолол

$C_{21}H_{32}N_2O$ = 328.5.

CAS — 10418-03-8.

ATC — A14AA02.

ATC Vet — QA14AA02.



NOTE. The following terms have been used as 'street names' (see p.vi) or slang names for various forms of stanozolol:
Iron Brew.

Pharmacopoeias. In *Chin.* and *US.*

USP 31 (Stanozolol). An odourless crystalline powder occurring in 2 forms; needles melt at about 155° and prisms at about 235°. Insoluble in water; soluble 1 in 41 of alcohol, 1 in 74 of chloroform, and 1 in 370 of ether; slightly soluble in acetone and in ethyl acetate; soluble in dimethylformamide; very slightly soluble in benzene. Store in airtight containers. Protect from light.

Adverse Effects and Precautions

As for androgens and anabolic steroids in general (see Testosterone, p.2130). As with other 17α-alkylated compounds stanozolol may produce hepatotoxicity, and liver function should be monitored. It is probably best avoided in patients with hepatic impairment, and certainly if this is severe. Haematocrit and haemoglobin concentrations should also be monitored.

Because of its androgenic effects it has been recommended that stanozolol should not be used to treat hereditary angioedema in premenopausal women except in life-threatening situations.

Effects on the kidney. Renal failure with cholestatic jaundice has been reported with stanozolol (see below).

Effects on the liver. Cholestatic jaundice has been reported with stanozolol,[1-3] in some cases with acute tubular necrosis and renal failure.[4]

1. Slater SD, *et al.* Jaundice induced by stanozolol hypersensitivity. *Postgrad Med J* 1976; **52:** 229–32.
2. Evely RS, *et al.* Severe cholestasis associated with stanozolol. *BMJ* 1987; **294:** 612–13.
3. Martínez B, *et al.* Colestasis inducida por consumo de estanozolol. *Rev Esp Enferm Dig* 2006; **98:** 219–20.
4. Yoshida EM, *et al.* At what price, glory? Severe cholestasis and acute renal failure in an athlete abusing stanozolol. *Can Med Assoc J* 1994; **151:** 791–3.

Effects on the nervous system. Benign intracranial hypertension developed in an elderly woman receiving stanozolol; CSF pressure returned to normal after stanozolol was stopped.[1]

1. Tully MP, *et al.* Intracranial hypertension associated with stanozolol. *DICP Ann Pharmacother* 1990; **24:** 1234.

Porphyria. Stanozolol is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in *animals*.

Interactions

As mentioned under Testosterone, p.2131, anabolic steroids may enhance the activity of a number of drugs. For the effect of stanozolol on some anticoagulants, see p.1431.

Uses and Administration

Stanozolol has anabolic and androgenic properties (see Testosterone, p.2131). As with other anabolic steroids, stanozolol has been used for breast cancer in postmenopausal women, and for anaemias, osteoporosis, and catabolic disorders. It has been given in oral doses of 2 mg every 8 to 12 hours, or 50 mg by intramuscular injection every 2 or 3 weeks.

In the management of hereditary angioedema, an initial oral dose of 2.5 to 10 mg daily has been given to prevent attacks. The dosage may then be reduced, according to the patient's response; maintenance doses of 2 mg daily or on alternate days, or 2.5 mg three times weekly have been used successfully. For doses that have been used in children, see below.

Administration in children. Androgens are usually avoided in children with hereditary angioedema (below) because of their adverse effects, but they have been used when other treatments are ineffective. In the USA oral doses of stanozolol 1 mg daily, given only during an attack, have been used in children under 6 years of age, and up to 2 mg daily in those aged 6 to 12 years. Slightly higher doses have been permitted in children in the UK.

Hereditary angioedema. Stanozolol raises serum concentrations of C1 esterase inhibitor and has been used successfully to prevent attacks of hereditary angioedema (p.1081).

References.

1. Bowen T, *et al.* Canadian 2003 international consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. *J Allergy Clin Immunol* 2004; **114:** 629–37.
2. Zuraw BL. Current and future therapy for hereditary angioedema. *Clin Immunol* 2005; **114:** 10–16.
3. Gompels MM, *et al.* C1 inhibitor deficiency: consensus document. *Clin Exp Immunol* 2005; **139:** 379–94. Correction. *ibid.*; **141:** 189–90. [dose]

Vascular disorders. Stanozolol has been used in the treatment of vascular manifestations of Behçet's syndrome. It has also been reported to promote fibrinolysis in vascular disorders, and has been tried in various conditions. However, most studies have been noncomparative and in small numbers of patients, and results have been variable.

Preparations

BP 2008: Stanozolol Tablets;
USP 31: Stanozolol Tablets.

Proprietary Preparations (details are given in Part 3)
Gr.: Stromba; ***India:*** Menabol; Neurabol; ***Irl.:*** Stromba†; ***Spain:*** Winstrol; ***Thai.:*** Stanol†; ***USA:*** Winstrol†.

Multi-ingredient: ***Thai.:*** Cetabon.

Testis Extracts ⊗

Extractos testiculares; Testicular Extracts.

Тестикулярный Экстракт

Profile

Testis extracts are usually of bovine origin and have been used in a variety of disorders. They have been given to elderly men as androgenic supplements. They have also been used topically, often in preparations containing other mammalian tissue extracts, in the treatment of peripheral circulatory or musculoskeletal disorders.

Preparations

Proprietary Preparations (details are given in Part 3)
Ger.: Orchibion†.

Multi-ingredient: ***Canad.:*** ratio-Heracline; ***Ger.:*** poliomyelan†; tactunerval†; ***Hong Kong:*** Wari-Procomil; ***Thai.:*** Wari-Procomil†.

Testosterone *(BAN, rINN)* ⊗

Testosteron; Testosterona; Testosteronas; Testostérone; Testosteroni; Testosteronum; Tesztoszteron. 17β-Hydroxyandrost-4-en-3-one.

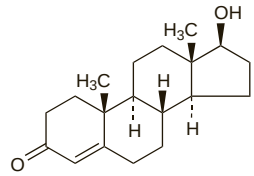
Тестостерон

$C_{19}H_{28}O_2$ = 288.4.

CAS — 58-22-0.

ATC — G03BA03.

ATC Vet — QG03BA03.



NOTE. The following terms have been used as 'street names' (see p.vi) or slang names for various forms of testosterone:
T-Stoff.

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

Ph. Eur. 6.2 (Testosterone). A white or almost white, crystalline powder, or colourless or yellowish-white crystals. Practically insoluble in water and in fatty oils; freely soluble in alcohol and in dichloromethane. Protect from light.

USP 31 (Testosterone). White or slightly creamy-white, odourless, crystals or crystalline powder. Practically insoluble in water; soluble 1 in 6 of dehydrated alcohol, 1 in 2 of chloroform, and 1 in 100 of ether; soluble in dioxan and in vegetable oils. Store at a temperature of 25°, excursions permitted between 15° and 30°.

Testosterone Cipionate *(BANM, rINNM)* ⊗

Cipionato de testosterona; Testostérone, Cipionate de; Testosterone Cyclopentylpropionate; Testosterone Cypionate; Testosteroni Cipionas. 3-Oxoandrost-4-en-17β-yl 3-cyclopentylpropionate; 17β-Hydroxyandrost-4-en-3-one cyclopentanepropionate; 17β-(3-Cyclopentyl-1-oxopropoxy)androst-4-en-3-one.

Тестостерона Ципионат

$C_{27}H_{40}O_3$ = 412.6.

CAS — 58-20-8.

ATC — G03BA03.

ATC Vet — QG03BA03.

Pharmacopoeias. In *US.*

USP 31 (Testosterone Cypionate). A white or creamy-white, crystalline powder, odourless or has a slight odour. Insoluble in water; freely soluble in alcohol, in chloroform, in dioxan, and in ether; soluble in vegetable oils. Protect from light.