

fluid retention or adverse effect on renal function or serum-lipids. In these reports, intramuscular doses of nandrolone decanoate have ranged from 100 mg once every 2 weeks<sup>1</sup> up to 600 mg weekly,<sup>2</sup> and treatment has generally been given for 12 to 24 weeks.

- Gold J, *et al.* Safety and efficacy of nandrolone decanoate for treatment of wasting in patients with HIV infection. *AIDS* 1996; **10**: 745-52.
- Sattler FR, *et al.* Effects of pharmacological doses of nandrolone decanoate and progressive resistance training in immunodeficient patients infected with human immunodeficiency virus. *J Clin Endocrinol Metab* 1999; **84**: 1268-76.
- Storer TW, *et al.* A randomized, placebo-controlled trial of nandrolone decanoate in human immunodeficiency virus-infected men with mild to moderate weight loss with recombinant human growth hormone as active reference treatment. *J Clin Endocrinol Metab* 2005; **90**: 4474-82.
- Mulligan K, *et al.* Effect of nandrolone decanoate therapy on weight and lean body mass in HIV-infected women with weight loss: a randomized, double-blind, placebo-controlled, multicenter trial. *Arch Intern Med* 2005; **165**: 578-85.
- Gold J, *et al.* Effects of nandrolone decanoate compared with placebo or testosterone on HIV-associated wasting. *HIV Med* 2006; **7**: 146-55.
- Johansen KL, *et al.* Anabolic effects of nandrolone decanoate in patients receiving dialysis: a randomized controlled trial. *JAMA* 1999; **281**: 1275-81.
- Johansen KL, *et al.* Effects of resistance exercise training and nandrolone decanoate on body composition and muscle function among patients who receive hemodialysis: a randomized, controlled trial. *J Am Soc Nephrol* 2006; **17**: 2307-14.
- Eiam-Ong S, *et al.* Nutritional effect of nandrolone decanoate in predialysis patients with chronic kidney disease. *J Ren Nutr* 2007; **17**: 173-8.

**Male contraception.** Preliminary findings showed that nandrolone suppressed spermatogenesis,<sup>1-3</sup> suggesting potential as a male contraceptive (p.2070), but later studies seem to have favoured other androgens.

- Schürmeyer T, *et al.* Reversible azoospermia induced by the anabolic steroid 19-nortestosterone. *Lancet* 1984; **i**: 417-20.
- Knuth UA, *et al.* Combination of 19-nortestosterone-hexyloxyphenyl-propionate (Anadur) and depot-medroxyprogesterone-acetate (Clinovir) for male contraception. *Fertil Steril* 1989; **51**: 1011-18.
- WHO Task Force on Methods for the Regulation of Male Fertility. Comparison of two androgens plus depot-medroxyprogesterone acetate for suppression to azoospermia in Indonesian men. *Fertil Steril* 1993; **60**: 1062-8.

### Preparations

**BP 2008:** Nandrolone Decanoate Injection; Nandrolone Phenylpropionate Injection;

**USP 31:** Nandrolone Decanoate Injection; Nandrolone Phenylpropionate Injection.

### Proprietary Preparations (details are given in Part 3)

**Arg.:** Deca-Durabolin; Keratyl†; **Austral.:** Deca-Durabolin; **Austria:** Deca-Durabolin; **Belg.:** Deca-Durabolin; **Braz.:** Deca-Durabolin; **Canad.:** Deca-Durabolin; **Chile:** Anaprolina; Deca-Durabolin; Nandrosande; **Cz.:** Deca-Durabolin; Keratyl†; Superanabolon; **Fin.:** Deca-Durabolin; **Fr.:** Keratyl†; **Ger.:** Deca-Durabolin; Keratyl†; **Gr.:** Anaboline Depot; Deca-Durabolin; Extraboline; Nurezan†; **Hong Kong:** Deca-Durabolin; **Hung.:** Retabolil; **India:** Deca-Durabolin; Decaneurabol†; Durabolin; Metabol; Metadec; **Neurabol; Indon.:** Deca-Durabolin; **Ital.:** Deca-Durabolin; Dynabolon†; **Malaysia:** Deca-Durabolin; **Mex.:** Deca-Durabolin; **Neth.:** Deca-Durabolin; Durabolin; **Norw.:** Deca-Durabolin; **NZ:** Deca-Durabolin; **Pol.:** Deca-Durabolin; **Port.:** Deca-Durabolin; Nandiant†; **Rus.:** Retabolil (Ретаболил); **S.Afr.:** Deca-Durabolin; **Singapore:** Deca-Durabolin; **Spain:** Deca-Durabolin; **Swed.:** Deca-Durabol; **Switz.:** Deca-Durabolin; Keratyl; **Thal.:** Deca-Durabolin; Keratyl; **UK:** Deca-Durabolin; **USA:** Androlone-D; Deca-Durabolin; Durabolin; Hylbolin; Neo-Durabolic; **Venez.:** Deca-Durabolin.

**Multi-ingredient:** **Arg.:** Dextapic†; **Indon.:** Dextapic; **Neth.:** Dextapic†.

### Nomegestrol Acetate (BANM, rINN)

Acetato de nomegestrol; Nomegestrol acétat; Nomégestrol, acétate de; Nomegestrol Asetat; Nomegestrolacetat; Nomegestrol acetat; Nomegestrolisetaatti; Nomegestrol acetatas; Nomegestrol-acetát. 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione acetate.

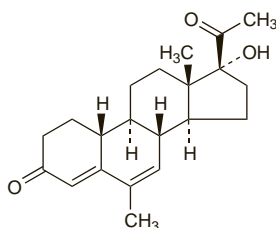
Номегестрола Ацетат

$C_{23}H_{30}O_4 = 370.5$ .

CAS — 58691-88-6 (nomegestrol); 58652-20-3 (nomegestrol acetate).

ATC — G03DB04.

ATC Vet — QG03DB04.



(nomegestrol)

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

**Ph. Eur. 6.2** (Nomegestrol Acetate). A white or almost white crystalline powder. Practically insoluble in water; soluble in alcohol; freely soluble in acetone. Protect from light.

### Profile

Nomegestrol acetate is a progestogen structurally related to progesterone (p.2125) that has been used in the treatment of menstrual disorders and as the progestogen component of menopausal HRT (p.2071). Typical oral doses are 5 mg daily for 10 to 14 days of a 28-day cycle. A subdermal implant is under investigation as a long-acting progestogen-only contraceptive.

### References

- Coutinho EM, *et al.* Multicenter clinical trial on the efficacy and acceptability of a single contraceptive implant of nomegestrol acetate, Uniplant. *Contraception* 1996; **53**: 121-5.
- Devoto L, *et al.* Hormonal profile, endometrial histology and ovarian ultrasound assessment during 1 year of nomegestrol acetate implant (Uniplant). *Hum Reprod* 1997; **12**: 708-13.
- Barbosa IC, *et al.* Carbohydrate metabolism in sickle cell patients using a subdermal implant containing nomegestrol acetate (Uniplant). *Contraception* 2001; **63**: 263-5.
- Arowojolu AO, Ladipo OA. Nonmenstrual adverse events associated with subdermal contraceptive implants containing nomegestrol [sic] and levonorgestrel. *Afr J Med Med Sci* 2003; **32**: 27-31.
- Barbosa IC, *et al.* Effects of a single Silastic contraceptive implant containing nomegestrol acetate (Uniplant) on endometrial morphology and ovarian function for 1 year. *Contraception* 2006; **74**: 492-7.

### Preparations

#### Proprietary Preparations (details are given in Part 3)

**Arg.:** Luteny†; **Belg.:** Luteny†; **Braz.:** Luteni†; **Chile:** Luteny†; **Cz.:** Luteny†; **Hong Kong:** Luteny†; **Indon.:** Luteny†; **Ital.:** Luteny†; **Mex.:** Luteny†; **Mon.:** Luteny†; **Pol.:** Luteny†; **Port.:** Luteny†; **Turk.:** Luteny†; **Venez.:** Luteny†.

**Multi-ingredient:** **Ital.:** Naemis; **Mon.:** Naemis; **Neth.:** Naemis; **Port.:** Naemis.

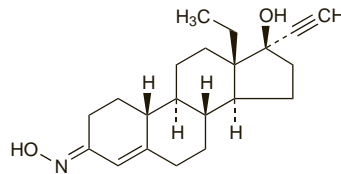
### Norelgestromin (BAN, USAN, rINN)

17-Deacetylorgestimate; Norelgestromini; Norelgestromina; Norelgestromine; Norelgestrominum; RWJ-10553. 13-Ethyl-17-hydroxy-18,19-dinor-17 $\alpha$ -pregn-4-en-20-yn-3-one oxime.

Норэльгестромин

$C_{21}H_{29}NO_2 = 327.5$ .

CAS — 53016-31-2.



### Profile

Norelgestromin is a progestogen (see Progesterone, p.2125); it is the primary active metabolite of norgestimate (p.2121). Norelgestromin is used as the progestogenic component of a combined contraceptive transdermal patch. A dose of 150 micrograms of norelgestromin is released daily with ethinylestradiol. A new patch is applied each week for 3 weeks of a 4-week cycle. Norelgestromin exposure from such a patch may be greater than that resulting from a comparable oral contraceptive.

### References

- Audet M-C, *et al.* Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs an oral contraceptive: a randomized controlled trial. *JAMA* 2001; **285**: 2347-54.
- Abrams LS, *et al.* Pharmacokinetics of norelgestromin and ethinyl estradiol from two consecutive contraceptive patches. *J Clin Pharmacol* 2001; **41**: 1232-7.
- Abrams LS, *et al.* Pharmacokinetics of norelgestromin and ethinyl estradiol delivered by a contraceptive patch (Ortho Evra /Evra ) under conditions of heat, humidity, and exercise. *J Clin Pharmacol* 2001; **41**: 1301-9.
- Abrams LS, *et al.* Pharmacokinetics of a contraceptive patch (Evra /Ortho Evra ) containing norelgestromin and ethinylestradiol at four application sites. *Br J Clin Pharmacol* 2002; **53**: 141-6.
- Burkman RT. The transdermal contraceptive system. *Am J Obstet Gynecol* 2004; **190** (suppl): S49-S53.
- Devenini D, *et al.* Pharmacokinetics and pharmacodynamics of a transdermal contraceptive patch and an oral contraceptive. *J Clin Pharmacol* 2007; **47**: 497-509.
- Jick S, *et al.* Further results on the risk of nonfatal venous thromboembolism in users of the contraceptive transdermal patch compared to users of oral contraceptives containing norgestimate and 35  $\mu$ g of ethinyl estradiol. *Contraception* 2007; **76**: 4-7.

### Preparations

#### Proprietary Preparations (details are given in Part 3)

**Multi-ingredient:** **Arg.:** Evra; **Belg.:** Evra; **Braz.:** Evra; **Canad.:** Evra; **Chile:** Evra; **Cz.:** Evra; **Denm.:** Evra; **Fin.:** Evra; **Fr.:** Evra; **Ger.:** Evra; **Gr.:** Evra; **Hong Kong:** Evra; **Hung.:** Evra; **Irl.:** Evra; **Israel:** Evra; **Ital.:** Evra;

**Mex.:** Evra; **Neth.:** Evra; **Norw.:** Evra; **Philipp.:** Evra; **Pol.:** Evra; **Port.:** Evra; **Rus.:** Evra (Espal); **S.Afr.:** Evra; **Singapore:** Evra; **Spain:** Evra; **Swed.:** Evra; **Switz.:** Evra; **Thal.:** Evra; **UK:** Evra; **USA:** Ortho Evra; **Venez.:** Evra.

### Norethandrolone (BAN, rINN) Ⓣ

17 $\alpha$ -Ethyl-17 $\beta$ -hydroxyestr-4-en-3-one; 17 $\beta$ -Hydroxy-19-nor-17 $\alpha$ -pregn-4-en-3-one; Noretandrolona; Noréthandrolone; Norethandrolonum.

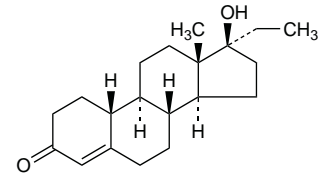
Норэтандролон

$C_{20}H_{30}O_2 = 302.5$ .

CAS — 52-78-8.

ATC — A14AA09.

ATC Vet — QAI4AA09.



### Adverse Effects and Precautions

As for androgens and anabolic steroids in general (see Testosterone, p.2130). As with other 17 $\alpha$ -alkylated compounds, norethandrolone may produce hepatotoxicity and liver function should be monitored. It should probably be avoided in patients with impaired liver function, and certainly if this is severe.

### Uses and Administration

Norethandrolone is an anabolic steroid with some androgenic properties (see Testosterone, p.2131). It is given in the treatment of aplastic anaemia in an oral dose of 0.25 to 2 mg/kg daily.

### Preparations

#### Proprietary Preparations (details are given in Part 3)

**Fr.:** Nlievar.

### Norethisterone (BAN, pINN)

Ethinylortestosterone; Etinil hidroxiestrona; Etinilortestosterona; Norethindrone; Norethisteron; Noréthistérone; Norethisteronum; Noretindrona; Noretisteron; Noretisterona; Noretisteronas; Noretisterone; Noretisteroni; Noretiszteron; Noretysteron; Norpregneninolona; Norpregneninolone; NSC-9564. 17 $\beta$ -Hydroxy-19-nor-17 $\alpha$ -pregn-4-en-20-yn-3-one.

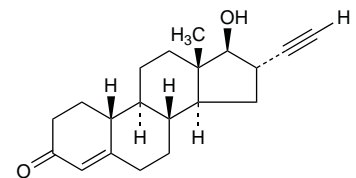
Норэтистерон

$C_{20}H_{26}O_2 = 298.4$ .

CAS — 68-22-4.

ATC — G03AC01; G03DC02.

ATC Vet — QG03AC01; QG03DC02.



**Pharmacopoeias.** In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn.* and *US*. **Ph. Eur. 6.2** (Norethisterone). A white or yellowish-white crystalline powder. Practically insoluble in water; sparingly soluble in dehydrated alcohol and in acetone; soluble in dichloromethane.

**USP 31** (Norethindrone). A white to creamy-white odourless crystalline powder. Practically insoluble in water; sparingly soluble in alcohol; soluble in chloroform and in dioxan; slightly soluble in ether.

### Norethisterone Acetate (BANM, pINN)

Acetato de noretisterona; Norethindrone Acetate; Norethisteron-acetát; Noréthistérone, acétate de; Norethisteroni acetat; Noretisteron Asetat; Noretisteronacetat; Noretisteroniasetatti; Noretisterono acetatas; Noretiszteron-acetát. 17 $\beta$ -Hydroxy-19-nor-17 $\alpha$ -pregn-4-en-20-yn-3-one acetate; 3-Oxo-19-nor-17 $\alpha$ -pregn-4-en-20-yn-17 $\beta$ -yl acetate.

Норэтистерона Ацетат

$C_{23}H_{28}O_3 = 340.5$ .

CAS — 51-98-9.

ATC — G03AC01; G03DC02.

ATC Vet — QG03AC01; QG03DC02.

### Pharmacopoeias.

In *Eur.* (see p.vii), *Int.*, and *US*. **Ph. Eur. 6.2** (Norethisterone Acetate). A white or yellowish-white crystalline powder. It exhibits polymorphism. Practically insoluble in water; soluble in alcohol; freely soluble in dichlo-