Maxigan (Максиган); Nebalgan (Небалган); Pentalgin-N (Пенталгин-Н); Revalgin (Ревалгин); Sedal-M (Седал-М); Sedalgin-Neo (Седальгин-Нео); Spasgan (Спазган); Spasmalgon (Спазмалгон); Spasmalin (Спазмалин); Buscopan Compositum; Norifortan†; Scopex Co; Spain: Buscapina Compositum; Norifortan†; Scopex Co; Spain: Buscapina Compositum; Nolotil Compositum†; That.; Butarion; Novapam; Turk.: Buscopan pan Compositum; Perajlin; Skopolin; **Venez.**: Bort†; Buscapina Composi-tum; Butilamina Compuesta; Cotar†; Diezol Compuesto†; Flemibar; Hioscinol Compuesto†; Praxona; Sarifan Compuesto†; Sistalcin Composi-

Eltenac (HNN)

Elténac; Eltenaco; Eltenacum. 4-(2,6-Dichloroanilino)-3-thiopheneacetic acid

 $C_{12}H_9Cl_2NO_2S = 302.2.$ CAS — 72895-88-6.

Profile

Eltenac is an NSAID (p.96) used in veterinary medicine.

Embutramide (BAN, USAN, rINN)

Embutramida; Embutramidum; Hoe-18-680. N-(β,β-Diethyl-mmethoxyphenethyl)-4-hydroxybutyramide.

Эмбутрамид

 $C_{17}H_{27}NO_3 = 293.4.$ CAS — 15687-14-6.

Profile

Embutramide is an opioid analgesic used in veterinary medicine for euthanasia.

Enoxolone (BAN, rINN)

Enoksolonas; Enoksoloni; Enoxolon; Enoxolona; Énoxolone; Enoxolonum; Glycyrrhetic Acid; Glycyrrhetinic Acid; Kwas glicyryzynowy. 3β-Hydroxy-11-oxo-olean-12-en-30-oic acid.

Эноксолон

 $C_{30}H_{46}O_4 = 470.7$ CAS — 471-53-4. ATC — D03AX10. ATC Vet - QD03AX10.

NOTE. Do not confuse with glycyrrhizic acid (p.2316).

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

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

Enoxolone is a complex triterpene prepared from glycyrrhizic acid (p.2316), a constituent of liquorice (p.1740). Enoxolone is used locally in preparations for the treatment of non-infective in-

flammatory disorders of the skin, mouth, throat, and rectum. Enoxolone potassium (potassium glycyrrhetinate) has been used similarly.

Derivatives of enoxolone, including its aluminium salt (p.1729) and carbenoxolone (p.1714) have been used in the treatment of benign peptic ulcer disease and other gastrointestinal disorders.

♦ Enoxolone is a potent inhibitor of the enzyme 118-hydroxysteroid dehydrogenase, which inactivates cortisol, and use with hydrocortisone has been shown in animal studies to potentiate the activity of hydrocortisone in skin.1 Whether this also increased the systemic absorption and toxicity of hydrocortisone was unclear.2 However, for reference to adverse effects attributed to systemic inhibition of cortisol when enoxolone (glycyrrhetinic acid) is produced during metabolism of ingested liquorice, see Effects on Fluid and Electrolyte Homoeostasis, p.1740.

A cream containing enoxolone with hyaluronic acid, telmesteine, and a grape extract, has been investigated with apparent benefit in the management of mild to moderate eczema.3 ever, topical application of enoxolone has been associated with contact dermatitis.5

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 Greaves MW. Potentiation of hydrocortisone activity in skin by glycerrhetinic acid. Lancet 1990; 336: 876.
- S. Belloni G, et al. A randomised, double-blind, vehicle-controlled study to evaluate the efficacy and safety of MAS063D (Atopiclair) in the treatment of mild to moderate atopic dermatitis. Eur
- clair) in the treatment of finite to moderate adopts curriantia. Earl J Dermatol 2005; 15: 31–6.

 4. Abramovits W, Boguniewicz M, Adult Atopiclair Study Group. A multicenter, randomized, vehicle-controlled clinical study to examine the efficacy and safety of MAS063DP (Atopiclair) in the management of mild to moderate atopic dermatitis in adults.
- J Drugs Dermatol 2006; 5: 236–44.

 Tanaka S, et al. Allergic contact dermatitis from enoxolone.

 Contact Dermatitis 2001; 44: 192.

Preparations

Proprietary Preparations (details are given in Part 3) Belg.: Dermanox; Fr.: Arthrodont; Moustidose; PO 12; S.Afr.: Arthro-

Multi-ingredient: Arg.: Anastim con RTH; Empecid Pie; Chile: Gingilacer; Ruboril; Sebium AKN; Suavigel; Fr.: Apaisance; Erygine; Fluocaril dents sensibles; Hexalyse; Hyseke; Hyseke Solaire; Mousticologne; Moustidose Bebe-Nourrisson; Night Peel; Novophane; Novophane S; Photoderm Bebe-Nourrisson; Night Peel; Novophane; Novophane S; Photoderm Luser; Pyreflor; Sebuim AKN; Sedorrhoide; Tiq/Aouta; Vocadys; Hong Kong: Hexalyse; Indon.: Polik; Israel: Aphtagone; Aptha-X; Gelclair; Ital: Acnesan; Bactilene; Benodent Gel Gengivale; Biothymus DS; Eudent con Glysan; Fluocani; Lenipasat; Lenipaset; Isiomuoli Gola; Neo-Stornygen; Pastiglie Valda; Prurex; Skab 2; Viderm; Mex.: Angenovag Periodenty; Port.: Despigmentante; Rus.: Hexalyse (Fexcavas); Spain: Angilepto; Anginovag; Roberfarin; UK: Atopiclair; Gelclair; Xclair; USA: Atopiclair; Gelclair; Yenez.: Sebium AKN; Sensibio DS.

Epirizole (USAN, pINN)

DA-398; Epirizol; Épirizole; Epirizolum; Mepirizole. 4-Methoxy-2-(5-methoxy-3-methylpyrazol-I-yl)-6-methylpyrimidine.

Эпиризол $C_{11}H_{14}N_4O_2 = 234.3.$ - 18694-40-1.

Pharmacopoeias. In Jpn.

Epirizole is an NSAID (p.96) that has been given in a usual oral dose of 150 to 450 mg daily in divided doses; larger doses of up to 600 mg daily have been used in patients with rheumatoid ar

Preparations

Proprietary Preparations (details are given in Part 3) Braz.: Mebron†; Jpn: Mebron; Venez.: Dale:

Etanercept (BAN, USAN, rINN)

Étanercept; Etanerceptum; Etanersept; Etanersepti; rhu-TNFR:Fc; TNR-001. A dimer of 1-235 tumour necrosis factor receptor (human) fusion protein with 236-467-immunoglobulin GI (human yI-chain Fc fragment).

Этанерцепт

CAS — 185243-69-0. ATC - LO4ABOI. ATC Vet - QL04AB01.

Adverse Effects and Precautions

As for Infliximab, p.69.

Mild to moderate injection site reactions with symptoms of erythema, itching, pain, or swelling are common with etanercept. Other common reactions include headache, dizziness, asthenia, nausea and vomiting, abdominal pain, dyspepsia, and allergic reactions. Antibodies to etanercept may develop.

Etanercept should be used with caution in patients with heart failure.

♦ References

Sánchez Carazo JL, et al. Safety of etanercept in psoriasis: a critical review. Drug Safety 2006; 29: 675–85.

Wegener's granulomatosis. The addition of etanercept to standard therapy (including cyclophosphamide or methotrexate and corticosteroids) was not shown to be effective in patients with Wegener's granulomatosis and was associated with an increased incidence of various non-cutaneous malignancies.1 Licensed product information recommends that etanercept should not be added to therapy in patients with Wegener's granulomato-

Wegener's Granulomatosis Etanercept Trial (WGET) Research Group. Etanercept plus standard therapy for Wegener's granulo-matosis. N Engl J Med 2005; 352: 351–61.

Interactions

As for Infliximab, p.71. The use of etanercept with sulfasalazine has resulted in decreased white blood cell counts; however, the clinical significance of this is unknown. For an increased incidence of malignancy when etanercept was added to standard immunosuppressive therapy in patients with Wegener's granulomatosis, see above.

Pharmacokinetics

After a single subcutaneous dose of etanercept, UK licensed product information states that the mean halflife is about 70 hours, and the time to peak serum concentration 48 hours. In contrast, US information gives the half-life as 102 hours and the time to peak concentration as about 70 hours, although with a considerable range. Repeated dosing was noted to result in a two-to sevenfold increase in serum levels of etanercept in some patients.

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- Nestorov I, et al. Pharmacokinetics of subcutaneously administered etanercept in subjects with psoriasis. Br J Clin Pharmacol 2006; **62**: 435-45.
- 7. Elewski B, et al. Comparison of clinical and pharmacokinetic profiles of etanercept 25 mg twice weekly and 50 mg once weekly in patients with psoriasis. Br J Dermatol 2007; 156: 138–42.

Uses and Administration

Etanercept is a recombinant version of soluble human tumour necrosis factor (TNF) receptor that binds specifically to tumour necrosis factor (p.783) and blocks its interaction with endogenous cell-surface TNF receptors. This interaction prevents the important effect of TNF in the inflammatory processes of rheumatoid arthritis; elevated TNF levels are also found in psoriatic plaques, in the synovium of patients with psoriatic arthritis, and in the serum and synovium of patients with ankylosing spondylitis.

Etanercept is used in the treatment of moderately to severely active rheumatoid arthritis and active and progressive psoriatic arthritis. In the UK, it is licensed for use in patients who have had an inadequate response to standard disease-modifying antirheumatic drugs although, in severe rheumatoid arthritis, it may be used in patients not previously treated with methotrexate. In the USA, it is licensed to treat early rheumatoid arthritis or psoriatic arthritis, to reduce the signs

and symptoms, delay structural damage, and improve physical function. In both indications, it is given as a subcutaneous injection in a dose of 25 mg twice weekly at intervals of 3 or 4 days. The equivalent weekly dose of 50 mg may also be given either as a single 50-mg injection or as two separate 25-mg injections (given at about the same time). In the UK, NICE recommends, based on guidelines from the British Society of Rheumatology, that treatment be stopped if there is no adequate response after 6 months. Etanercept is also indicated in the treatment of severely active ankylosing spondylitis; in the UK, its use is again limited to those who have had an inadequate response to conventional therapy. Doses are similar to those used for rheumatoid arthritis.

Etanercept is also used in the treatment of chronic. moderate to severe plaque psoriasis. In the UK, its use is usually limited to patients in whom other systemic treatments are not suitable. The recommended initial dose is 25 mg twice weekly. Alternatively, an initial dose of 50 mg twice weekly at intervals of 3 or 4 days may be given for 12 weeks; the dose should then be reduced to 25 mg twice weekly or 50 mg weekly. Initial doses of 25 or 50 mg once weekly have also been shown to be effective. Treatment should continue until remission is achieved, for up to 24 weeks. Etanercept should be stopped after 12 weeks in patients who show no response.

For details of uses and dosage in children, see below.

Administration in children. Etanercept is used in the treatment of moderately to severely active polyarticular juvenile idiopathic arthritis; UK licensed product information limits its use to those who have had an inadequate response to, or who are intolerant of, the disease-modifying antirheumatic drug meth-

In the UK, it is given subcutaneously to children aged 4 years and over in a dose of 400 micrograms/kg (up to a maximum dose of 25 mg) twice weekly at intervals of 3 or 4 days. In the USA. etanercept is licensed for use in children as young as 2 years old. Similar doses are used although they are expressed as 800 micrograms/kg (up to a maximum dose of 50 mg) weekly: doses to be given as 2 separate injections may either be given on the same day or 3 to 4 days apart.

In the UK, NICE recommends, based on guidelines from the British Paediatric Rheumatology Group, that treatment be stopped in children if there is no response after 6 months, or an initial response is not maintained.

For references on the use of etanercept in juvenile idiopathic arthritis, see Rheumatoid Arthritis, below.

Asthma. TNF inhibitors such as etanercept have been investigated in the treatment of refractory asthma (p.1108).1,2 There is some evidence that only a minority of patients will respond to such therapy, and that the benefits and risks must therefore be carefully assessed.3

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- 2. Berry MA, et al. Evidence of a role of tumor necrosis factor α in
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 Brightling C, et al. Targeting TNF-α: a novel therapeutic approach for asthma. J Allergy Clin Immunol 2008; 121: 5–10.

Dementia. A small pilot study¹ and individual case reports² have suggested that perispinal injection of etanercept, in doses of 25 to 50 mg weekly, may improve signs of dementia in patients with Alzheimer's disease. However, randomised controlled studies are required to confirm any benefit.

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- imer's disease following perispinal etanercept administration. *J Neuroinflammation* 2008; **5:** 2.
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Psoriasis. Etanercept is effective in patients with moderate to severe plaque psoriasis (p.1583). ¹⁻⁹ It has also been successfully tried in the treatment of erythrodermic psoriasis, 10 and of plaque psoriasis in children and adolescents.11

Efficacy may be dose-related; in one study, 1 25% of patients in the low-dose (25 mg once weekly) group showed at least a 75% improvement compared with 44% in the medium-dose group (25 mg twice weekly) and 59% in the high-dose group (50 mg twice weekly) after 24 weeks of etanercept treatment. However, a later multicentre study² in patients with chronic plaque psoriasis found that the therapeutic effect of etanercept was maintained when the dose was reduced after 12 weeks from 50 mg twice weekly to 25 mg twice weekly. An open-label extension8 of

these 2 studies found that efficacy was also sustained when patients who had received etanercept 25 mg twice weekly for at least 24 weeks had their dose altered to 50 mg once weekly.

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- 1Artosguidance: put (accessed 13/00/09)
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- 7. Romero-Maté A, et al. Efficacy and safety of etanercept in psoriasis/psoriatic arthritis: an updated review. Am J Clin Dern
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Rheumatoid arthritis. Some references to the use of etanercept in rheumatoid arthritis (p.11) and juvenile idiopathic arthritis (p.10).

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- 4/8-80.
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- 343: 1380–93. Correction. *total.* 2001; 344: 76.

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Spondyloarthropathies. References to the use of etanercept in the treatment of ankylosing spondylitis and psoriatic arthritis

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Vasculitic syndromes. For a preliminary report on the use of etanercept in Takayasu's arteritis, see p.1514.

Preparations

Proprietary Preparations (details are given in Part 3)

Proprietary Preparations (details are given in Part 3)
Arg.: Enbrek, Austral.: Enbrek, Belg.: Enbrek, Braz.: Enbrek, Grad.: Enbrek,
Chile: Enbrek, Cz.: Enbrek, Denm.: Enbrek, Fin.: Enbrek, Fre: Enbrek,
Enbrek, Gr.: Enbrek, Hong Kong: Enbrek, India: Enbrek, Indon.: Enbrek, Inden.: Enbrek,
Enbrek, Israel: Enbrek, Ital.: Enbrek, Malaysia: Enbrek, Mex.: Enbrek,
Neth.: Enbrek, Norw.: Enbrek, NZ: Enbrek, Philipp.: Enbrek, Pol.: Enbrek,
Port.: Enbrek, S.Afr.: Enbrek, Singapore: Enbrek, Spain: Enbrek, Swed.:
Enbrek, Swetz: Enbrek, Thal.: Enbrek, Turk.: Enbrek, UK: Enbrek, UKA: Enbrek,
Venez.: Enbrek, Thal.: Enbrek, Turk.: Enbrek, UK: Enbrek, UK: Enbrek, Venez.: Enbrek,

Multi-ingredient: Hung.: Enbrel.

Ethenzamide (BAN, rINN)

Aethoxybenzamidum; Etentsamidi; Etenzamid; Etenzamida; Etenzamide; Éthenzamide; Ethenzamidum; Ethoxybenzamide; Ethylsalicylamide; HP-209. 2-Ethoxybenzamide.

Этензамид

 $C_9H_{11}NO_2 = 165.2.$ CAS — 938-73-8. ATC — N02BA07.

ATC Vet - QN02BA07.

Pharmacopoeias. In Jpn.

Ethenzamide is a salicylic acid derivative (see Aspirin, p.20) given by mouth in painful and inflammatory conditions and to reduce fever.