Ichthammol *(BAN)*

Ammonii Bituminosulfonas; Ammonii Sulfogyrodalas; Ammonio Sulfoittiolato; Ammonium Bithiolicum; Ammonium Bitumenosulfonicum; Ammonium Bituminosulphonate; Ammonium Ichthosulphonate; Ammonium Sulfobituminosum; Ammonium Sulpho-Ichthyolate; Amonowy sulfobituminian; Bithiolate Ammonique; Bithyol; Bitiol; Bitiolato amónico; Bitomol; Bituminol; Ichtammol; Ichtamolis; Ichthammolum; Ichthamol; Ichthosulphol; Ichthyol; Ichthyolammonium; Ictamol; Ictiolsulfonato amónico; Ihtamol; Iktammol; Iktammoli; Sulfobituminato amónico; Sulfoictiolato amónico.

Ихтаммол; Ихтиол

CAS — 8029-68-3.

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

Ph. Eur. 6.2 (Ichthammol). A dense blackish-brown liquid. It is obtained by distillation of certain bituminous schists, sulfonation of the distillate, and neutralisation of the product with ammonia. It contains not less than 4.5% and not more than 7.0% of total ammonia, not less than 10.5% of organically combined sulfur, calculated with reference to the dried substance, and not more than 20% of the total sulfur in the form of sulfates.

Miscible with water and with glycerol; slightly soluble in alcohol, in fatty oils, and in liquid paraffin; forms homogeneous mixtures with wool fat and soft paraffin.

USP 31 (Ichthammol). A reddish-brown to brownish-black viscous fluid with a strong characteristic empyreumatic odour. It is obtained by the destructive distillation of a bituminous schist, sulfonation of the distillate, and neutralisation of the product with ammonia. It yields not less than 10.0% of total sulfur and not less than 2.5% of ammonia. Miscible with water, with glycerol, and with fixed oils and fats. Partially soluble in alcohol and in ether.

Incompatibility. Ichthammol is incompatible with wool alcohols.

Profile

Ichthammol has slight bacteriostatic properties and is used in a wide range of topical preparations, for a variety of skin disorders; it has also been used in suppositories for anorectal disorders. Ichthammol is often used with zinc oxide in medicated bandages for chronic lichenified eczema (p.1579). Ichthammol may be slightly irritant to the skin and there have been rare reports of hypersensitivity.

Light Ammonium Bituminosulfonate (Ammoniumbituminosulfonat Hell) is produced from the light distillate fraction of shale oil.

Ammoniumsulfobitol, an ammonium bituminosulfonate similar to ichthammol but with a low sulfur content, was commercially available as Tumenol Ammonium.

Preparations

BP 2008: Zinc and Ichthammol Cream;
USP 31: Ichthammol Ointment.

Proprietary Preparations (details are given in Part 3)

Austral.: Egoderm; ***Austria:*** Ichtho-Bad; Ichtholan; Ichtopur; ***Belg.:*** Bithiol; Poudre Velours; ***Cz.:*** Ichtoxyl; ***Fr.:*** Gelictar†; ***Ger.:*** Ichtho-Bad; Ichtholan; Ichtholan spezial; Ichthyol; Thiobitum; ***Neth.:*** Daroderm Trekzalf; Trekzalf; ***Switz.:*** Ichtho-Bad; Ichtholan; ***Turk.:*** Ihtiyol; Pomat Ichthyole; Pommade Ichthyole.

Multi-ingredient: ***Arg.:*** Cicatrina; ***Austral.:*** Egoderm; Icthaband†; ***Austria:*** Aknemycin compositum; Delta-Hadensa; Hadensa; Ichth-Oestren; Inotyol; ***Belg.:*** Antipiol; Inotyol; ***Canad.:*** Boil Ease†; ***Cz.:*** Pityol; Saloxyl; ***Denm.:*** Inotyol; ***Fin.:*** Hadensa; ***Fr.:*** Anaxeryl; Gelictar Fort; Inotyol†; Node DS; Novophane S; Oxythyol; Phytheol; Phytolithe†; Provictol†; Selegel; Squaphane Masque-Creme; ***Ger.:*** Aknemycin; ***Hong Kong:*** Acnederm; Egoderm; ***Israel:*** Aknemycin; Inotyol; ***Ital.:*** Antiemorroidali; Dermatar; Ichthopaste; Inotyol†; Tricoderm F; ***Malaysia:*** Acnederm†; Egoderm; ***Norw.:*** Inotyol; ***NZ:*** Acnederm†; Egoderm; ***Pol.:*** Neo-Tormentil; Tormentile Forte; Tormentiol; ***Port.:*** Efluvium Anti-caspa; Efluvium Anti-seborreico; Oleoban Composto†; Pansebase Composto; Secpel Composto; ***Rus.:*** Bethiol (Бетиол); ***S.Afr.:*** Antipeol; ***Singapore:*** Egoderm; ***Spain:*** Hadensa; Ictiomen; Lamnotyl†; ***Swed.:*** Inotyol; ***Switz.:*** Aknemycin; Bain extra-doux dermatologique; Epithelial†; Furodermal; Leucen; Radix; Riccovitan†; ***Turk.:*** Hedensa; ***UK:*** Antipeol; Ichthopaste; Icthaband; St James Balm; ***USA:*** Boil Ease; Boyol Salve; Medicone Derma†; ***Venez.:*** Node DS.

Ictasol *(USAN)*

Ichtasol; Ichthyol-Natrium Hell; Light Sodium Bituminosulphonate; Natrium Sulfobituminosum Decoloratum; Sulfobituminato sódico; Sulfobituminato sódico decolorado.

$C_{28}H_{36}Na_2O_6S_3$ = 610.8.

CAS — 12542-33-5; 1340-06-3.

ATC — D10BX01.

ATC Vet — QD10BX01.

Profile

Ictasol is a sodium bituminosulfonate produced from the light distillate fraction of shale oil. Sodium bituminosulfonate is obtained by the destructive distillation of certain bituminous schists, sulfonation of the distillate, and neutralisation of the product with sodium hydroxide.

Ictasol has similar properties to ichthammol (above) and is used in a wide range of preparations for a variety of skin disorders.

Preparations

Proprietary Preparations (details are given in Part 3)

Austria: Crino Cordes; Ichthraletten; Lavichthol; ***Ger.:*** Aknichthol Creme; Crino Cordes N†; Dermichthol†; Ichthoderm; Ichtholan T; Ichthosin; Ichthraletten; Leukichtan; Solutio Cordes.

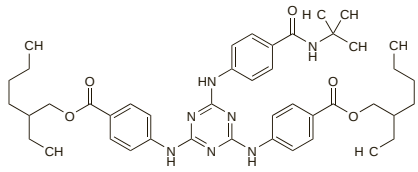
Multi-ingredient: ***Arg.:*** Selegel; ***Austria:*** Aknichthol; Ichthalgan forte; Ichtho-Bellol; Ichtho-Cortin; Leukichtan; ***Chile:*** Ichtyosoft†; ***Fr.:*** I-Soft†; Ichtyosoft†; Sebosquam; ***Ger.:*** Aknederm Neu; Aknichthol N; Ichthalgan†; Ichtho-Bellol compositum S†; Ichtho-Bellol†; Ichthocortin; Ichthoseptal; Pelvichthol N; ***Switz.:*** Aknichthol N.

Iscotrizinol *(USAN)*

Diethylhexyl Butamido Triazone; Diethylhexylbutamido Triazone; Dioctylbutamidotriazone. Bis(2-ethylhexyl) 4,4′-[(6-{[4-(*tert*-butylcarbamoyl)phenyl]amino}-1,3,5-triazine-2,4-diyl)diimino]dibenzoate.

$C_{44}H_{59}N_7O_5$ = 766.0.

CAS — 154702-15-5.



NOTE. Uvasorb HEB is a trade name that has been used for iscotrizinol.

Profile

Iscotrizinol is used as a sunscreen (p.1576). It is effective against UVB light (for definitions, see p.1580).

Preparations

Proprietary Preparations some preparations are listed in Part 3.

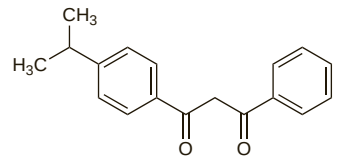
Isopropyldibenzoylmethane

Isopropildibenzoilmetano. 1-[4-(1-Methylethyl)phenyl]-3-phenyl-1,3-propanedione.

Изопропилдибензоилметан

$C_{18}H_{18}O_2$ = 266.3.

CAS — 63250-25-9.



Profile

Isopropyldibenzoylmethane, a substituted dibenzoylmethane, is a sunscreen (p.1576) with actions similar to those of avobenzone (p.1589). It is effective against UVA light (for definitions, see p.1580).

Preparations

Proprietary Preparations some preparations are listed in Part 3.

Isotretinoin *(BAN, USAN, rINN)*

Isotretinoiini; Isotretinoína; Isotrétinoïne; Isotretinoinum; Izotretinoin; Izotretinoinas; Izotretynoina; 13-*cis*-Retinoic Acid; Ro-4-3780. (13*Z*)-15-Apo-β-caroten-15-oic acid; (2*Z*,4*E*,6*E*,8*E*)-3,7-Dimethyl-9-(2,6,6-trimethylcyclohex-1-enyl)nona-2,4,6,8-tetraenoic acid.

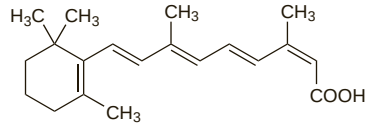
Изотретиноин

$C_{20}H_{28}O_2$ = 300.4.

CAS — 4759-48-2.

ATC — D10AD04; D10BA01.

ATC Vet — QD10AD04; QD10BA01.



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

Ph. Eur. 6.2 (Isotretinoin). A yellow or light orange, crystalline powder. Practically insoluble in water; slightly soluble in alcohol; soluble in dichloromethane. It is sensitive to air, heat, and light, especially in solution. Store in airtight containers at a temperature not exceeding 25°. Protect from light. It is recommended that the contents of an opened container be used as soon as possible and that any unused part be protected by an atmosphere of an inert gas.

USP 31 (Isotretinoin). Yellow crystals. Practically insoluble in water; sparingly soluble in alcohol, in isopropyl alcohol, and in macrogol 400; soluble in chloroform. Store in airtight containers under an atmosphere of an inert gas. Protect from light.

Adverse Effects

The adverse effects of isotretinoin and other oral retinoids are similar to those of vitamin A (see p.1971) and are generally reversible and dose-related. The most common are dryness of the mucous membranes and skin, which can often progress to cheilitis, epistaxis, conjunctivitis, localised exfoliation including palmoplantar exfoliation, pruritus, erythematous rash, and skin fragility. Less common effects have included hair thinning (occasionally irreversible), hirsutism, photosensitivity, changes in skin pigmentation, paronychia, nail dystrophy, pyogenic granuloma, and increased sweating. Acne can be exacerbated at the beginning of isotretinoin treatment, and there are very rare reports of acne fulminans occurring. Less common adverse effects on the eyes include corneal opacities, visual disturbances such as blurred vision and colour vision disorders, impaired night vision that may persist, photophobia, and keratitis. Papilloedema, visual disturbances, headache, and nausea and vomiting can be signs and symptoms of benign intracranial hypertension. Arthralgia, myalgia, and back pain are commonly reported, and there have been rare reports of arthritis, osteoporosis, and tendinitis. Hyperostosis and calcinosis have also occurred, particularly in patients treated with high doses of isotretinoin over long periods for keratinisation disorders. Premature closure of the epiphyses has occurred in children treated with isotretinoin. Elevation of serum triglycerides is common, and pancreatitis has occurred in patients with high concentrations; cholesterol concentrations may also be increased. Increases in hepatic enzymes, erythrocyte sedimentation rate, and blood glucose can also occur. Alterations in haematological measures are common; there have also been reports of anaemia, thrombocytopenia, and neutropenia, and very rare reports of agranulocytosis. Other effects that have been reported rarely include gastrointestinal symptoms, hepatitis, hearing impairment, drowsiness, seizures, vasculitis, and hypersensitivity reactions including anaphylaxis. Mood changes, psychotic symptoms, depression, and suicidal behaviour have occurred in patients treated with oral isotretinoin. There may also be an association with skin infections and an inflammatory bowel syndrome.

Isotretinoin and other retinoids are teratogenic.

When isotretinoin is applied topically the adverse effects are similar to those of tretinoin (see p.1618).

◊ General references.

1. Mills CM, Marks R. Adverse reactions to oral retinoids: an update. *Drug Safety* 1993; **9:** 280–90.
2. Keefe M. Adverse reactions profile: retinoids. *Prescribers' J* 1995; **35:** 71–6.
3. McLane J. Analysis of common side effects of isotretinoin. *J Am Acad Dermatol* 2001; **45:** S188–S194.
4. British Association of Dermatologists. Advice on the safe introduction and continued use of isotretinoin in acne (2003). Available at: http://www.bad.org.uk/healthcare/guidelines/acne.asp (accessed 27/09/07)
5. Charakida A, *et al.* Safety and side effects of the acne drug, oral isotretinoin. *Expert Opin Drug Saf* 2004; **3:** 119–29.
6. Goldsmith LA, *et al.* American Academy of Dermatology consensus conference on the safe and optimal use of isotretinoin: summary and recommendations. *J Am Acad Dermatol* 2004; **50:** 900–906. Correction. *ibid.*; **51:** 348. [dose]

Effects on the blood. Serious adverse effects on the blood have been reported rarely with oral retinoids, and are thought to be idiosyncratic in nature. There have been reports of thrombocytopenia in patients taking isotretinoin[1] and etretinate.[2,3] A few cases of agranulocytosis have involved isotretinoin[4] and acitretin.[5] In contrast, there are also reports of transient and asymptomatic thrombocytosis associated with isotretinoin[6] and tretinoin.[7,8] Leucocytosis is often associated with the retinoic acid syndrome caused by tretinoin (p.1618).

1. Moeller KE, Touma SC. Prolonged thrombocytopenia associated with isotretinoin. *Ann Pharmacother* 2003; **37:** 1622–4.
2. Naldi L, *et al.* Etretinate therapy and thrombocytopenia. *Br J Dermatol* 1991; **124:** 395.