Light Liquid Paraffin

Dünnflüssiges Paraffin; Hígan folyó paraffin; Huile de Vaseline Fluide; Light Liquid Petrolatum; Light Mineral Oil; Light White Mineral Oil; Paraff. Lig. Lev.; Paraffin, lättflytande; Paraffine liquide légère; Paraffinum Liquidum Leve; Paraffinum Liquidum Tenue; Paraffinum perliquidum: Parafini, keyyt nestemäinen: Parafin tekutý lehký; Skystasis lengvas parafinas; Spray Paraffin; Vaselina líquida.

ATC - A06AA01. ATC Vet - QA06AA01.

Pharmacopoeias. In Eur. (see p.vii) and Jpn. Also in USNF. US also includes Topical Light Mineral Oil .

Ph. Eur. 6.2 (Paraffin, Light Liquid). A purified mixture of liquid saturated hydrocarbons obtained from petroleum. It is a transparent, colourless, oily liquid, free from fluorescence in daylight. Relative density 0.810 to 0.875. Viscosity 25 to 80 mPa s. Practically insoluble in water; slightly soluble in alcohol; miscible with hydrocarbons. Protect from light.

USNF 26 (Light Mineral Oil). A purified mixture of liquid hydrocarbons obtained from petroleum. It may contain a suitable stabiliser. It has similar characteristics to Mineral Oil but a lower kinematic viscosity. Store in airtight containers. Protect from light.

Adverse Effects and Precautions

Excessive oral or rectal dosage with liquid paraffin may result in anal seepage and irritation, excessive purgation, and watery diarrhoea. Liquid paraffin is absorbed to a slight extent and may give rise to foreign-body granulomatous reactions. Similar reactions have followed the injection of liquid paraffin and may be considerably delayed in onset. Injection may also cause vasospasm and prompt surgical removal may be required to prevent severe damage. Lipoid pneumonia has been reported after aspiration of liquid paraffin. Because of the risk of aspiration, oral liquid paraffin should not be given to patients who have difficulty swallowing. or to those with impaired neurodevelopment.

Some licensed product information warns that chronic ingestion of liquid paraffin may rarely be associated with impaired absorption of fat-soluble vitamins and possibly other compounds. There is little published evidence to support this. Prolonged use should, however, be avoided. Liquid paraffin should not be used when abdominal pain, nausea, or vomiting is present. The UK CSM considers that it should not be used in children under 3 years of age.

Granuloma, References

Di Benedetto G, et al. Paraffin oil injection in the body: an obsolete and destructive procedure. Ann Plast Surg 2002; 49: 391–6.

Lipoid pneumonia. References.

- Becton DL, et al. Lipoid pneumonia in an adolescent girl second-ary to use of lip gloss. J Pediatr 1984; 105: 421–3.
- Ohwada A, et al. Exogenous lipoid pneumonia following ingestion of liquid paraffin. Intern Med 2002; 41: 483–6.
- Karacan O, et al. Fire-eater's pneumonia after aspiration of liquid paraffin. Turk J Pediatr 2006; 48: 85–8.
- 4. Meltzer E, et al. Lipoid pneumonia: a preventable complication. *Isr Med Assoc J* 2006; **8:** 33–5.

Uses and Administration

Taken orally, liquid paraffin acts as a lubricant and, since it keeps the stools soft, it has been used in the symptomatic treatment of constipation (p.1693), although it should be used with caution because of its adverse effects. The recommended daily oral dose is 10 to 30 mL in divided doses, preferably before breakfast and at night. An emulsion of liquid paraffin may also be used in a dose of 10 to 30 mL at night. Liquid paraffin and its preparations should not, however, be taken immediately before going to bed. Liquid paraffin is an ingredient of several preparations that contain other laxatives such as cascara, magnesium hydroxide, or phenolphthalein. It has also been given as an enema in a usual dose of 120 mL.

Externally, liquid paraffin may be used as an ingredient of ointment bases, as an emollient and cleanser in certain skin conditions, and as an ophthalmic lubricant in the management of dry eye (p.2140).

Light liquid paraffin has similar uses to liquid paraffin.

Administration in children. UK licensed product information gives the following oral doses of liquid paraffin for constipation in children, to be taken at night:

- · under 3 years: not recommended
- 3 to 5 years: 2.5 to 5 mL
- 5 to 12 years: 5 to 10 mL
- · over 12 years: as for adults

For light liquid paraffin, the BNFC recommends a daily oral dose of 0.5 to 1 mL/kg, up to a maximum of 45 mL, for children aged 3 to 18 years. It should be taken after the evening meal but not immediately before going to bed, and may be mixed with icecream or yogurt to improve palatability.

The BNFC gives the following oral doses of liquid paraffin emulsion, to be taken once daily but not immediately before going to bed:

- · under 3 years: not recommended
- 3 to 12 years: 0.5 to 1 mL/kg, up to a maximum of 30 mL
- · 12 to 18 years: as for adults

Preparations

BP 2008: Cetomacrogol Emulsifying Ointment; Cetrimide Emulsifying Ointment; Emulsifying Ointment; Light Liquid Paraffin Eye Drops; Liquid Paraffin and Magnesium Hydroxide Oral Emulsion; Liquid Paraffin Oral

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Proprietary Preparations (details are given in Part 3)

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Arg.: Babix, Lansoyi; Lax Ewe Jalea; Laxante Arceli; Laxuave Enteral; Laxuave Jalea; Laxarte; Lubritian Franklin; Modaton NI; Oilatum; Australi: Agarol; Hamilton Skin Therapy, Oilatum Bar; Oilatum Emollient; Oilatum Shower Gel; Belg.: Lansoyi; Braz.: Nujoi; Canad.: Fleet Enema Mineral Oil; Lansoyi; Nujoi; Cfille: Laxonarol; Cz.: Ollatum Emollient; Oilatum Gel; Fr.: Lansoyi; Laxamalt†; Lubentyi; Oilatum Emollient; Oilatum Soap†; Restrical; Ger.: Agarol; N‡; Obstinol MY; Gr.: Agarol Plain; Nujoi; Paragei; Hong Kong: Agarol; N‡; Obstinol MY; Gr.: Agarol Blain; Nujoi; Paragei; Hong Kong: Agarol; Hamilton Body Wash; Keri; Oilatum Bar; Oilatum Gel; Irl.: Akodem†; Oilatum Gel; Vigarol; Indon.: Oilatum Bar; Oilatum Gel; Irl.: Akodem†; Oilatum; Gel; Oilatum; Dol.: Oilatum; Pol.: Oilatum; Pol.: Oilatum; S.Afr.: Oilatum Bar; Oilatum Emollient; Dilatum; Pol.: Oilatum; S.Afr.: Oilatum Bar; Oilatum Emollient; Dilatum Gel; Spain: Emuliquen Simple; Hodernal; Switz.: Lansoyl; Laxamalt; Paragol N; Thai.: Agarol; Oilatum Bar; Oilatum Endlient; Oilatum Gel; Spain: Emuliquen Simple; Hodernal; Switz.: Lansoyl; Laxamalt; Paragol N; Thai.: Agarol; Oilatum Bar; Oilatum Gel; Oilatum Gel; Oilatum Soap; Zerobase; USA: Kondremu; Liqui-Doss.

grance Free; Oliatum Gel; Oilatum Junior; Oilatum Soap; Zerobase; USA: Kondremul; Liqui-Doss.

Multi-ingredient: Arg.: Agarol; Alcon Lagrimas; Aqualane; Cold Cream Naturel†; Mil-Par; Usar Fibras†; Austral.: Alpha Keri; DermaVeen Shower & Bath; Dermeze: Duratears; E45; Egozite Baby Cream; Granugen; Hamilton Body Lotion†; Hamilton Cleansing Lotion†; Hamilton Dry Skin; Lacri-Lube; Oilatum Plus; Parachoc; Pinetarsol; Rikoderm†; Soov Prickly Heat, Austria: Balneum F; Neda Fruchtewurfel; Belg.: Duratears; Lacrytube; Tulle Vaseline†; Braz.: Agarol; Balmex; Fenogar†; Parapsyi; Canad.: Agarol Plair; Akwa Tears, Alpha Keri†; Duolube; Duratears†; Episeç; Huile de Bain Therapeutique; Hypotears; Lubriderm Advanced Moisture†; Lubriderm†; Magnolax Oilatum; Optilube, Penderm†; Duralube†; Refresh Lacri-Lube; Tears Naturale PM; Therapeutic Bath Öil†; Therapeutic Skin Lotion†; Chile: Acnaid; Acnovaj Jabon†; Agarol; Cold Cream Avene; Durasolets; Duratears; Lacri-Lube; Cz.: Balmandol; Balneum Hermal F; Oilatum Plus Denm.: Ojensalve Neutral; Fin.: Lacri-Lube; Fr.: Cerat Inalterable; Cold Cream Nature†; Dexempt; Lubentyl a la Magnesie; Melaxose; Oilatum Body Oil†; Oilatum Cream; Parapsyllium; Transulose; Ger.: Allergika†; Balneum F; Cellosorb; Coliquiffin; Excipiak; Gletigelen; Oleobal; Parfena Basisbad†; Vita-POS; Windol Basisbad†; Gr.: Duratears; Hong Kong; Alpha Keri; Balneum; Duratears; Ego Skin Cream; Egozite Baby Cream; Hydromol†; Oilatum Plus; Yanthi Baby Oil; Inf.: Emulsiderm; Hydromol†; Lacri-Lube; Ollatum Plus; Yanthi Baby Oil; Inf.: Emulsiderm; Hydromol†; Lacri-Lube; Ollatum Plus; Polytar Emollient; Jarene; Balneum F; Cleanfars; Duratears; Emolsiderm; Lacrinol; Infal: Balneum Hermal Forte; Duolaxan†; Lacrilube; Oilatum Plus; Polytar Emollient; Salneum Hermal Forte; Duolaxan†; Lacrilube; Oilatum Plus; Polytar Emollient; Balneum Hermal Forte; Duolaxan†; Lacrilube; Oilatum Plus; Polytar Emollient; Balneum Hermal Forte; Duolaxan†; Lacrilube; Oilatum; Oilatum; Oilatum; Oilatum; Oilatum; Oilatum; Oilatum; Oilatum; Oilatum; Oilat Flus Singapore: Baineum; Dermaveen shower & Batm; Duratears; Skin Cream; Egozite Baby Cream; Egozite Protective Baby Lotion†; Lacrilube; Oilatum Plus; QV Flare Up; Soov Prickly Heat†; **Spain:** Aceite Acalorico; Emuliquen Laxante; Lubrifilm; Vaselatum; **Switz.**: Antidny; Balmand; Balmed Hermal F†; Coliquifilm; Paragar; Woloderma†; **Thai.**: Balneum†; Duratears; Emulax; Oilatum Cream; Oila-Wolodermat; Thoi.: Balneum;†: Duratears; Emulax; Oilatum Cream; Öilatum Plus; Turk.: Balmandol; UK: 50:50; Alpha Keri; Ashbourne Emollient Medicinal Bath Oil;†: Cetraben Emollient; Dermalo; Dermol; Diprobase; Diprobath; Doublebase; Emollin; Emulsiderm; Epaderm; Hydromol; Imuderm; Infaderm; Lari-Lube; Lubri-Tears; Nil-Par; Oilatum Cream; Oilatum Emollient; Oilatum Junior; Oilatum Junior Flare-Up;†; Oilatum Plus; Polytar Emollient; USA: Agoral; Akwa Tears; Alpha Keri; Bodi Care Lotion; Bodi Oil; Desitin Creamy; Dry Eyes; Duratears Naturale; Ger-Silk; Halley's M-O; Hemorid For Women; Hydrocerin; Hypotears; Lacri-Gel; Lacri-Lube; Lacti-care; Lubri-Fresh PM; Lubri-Tears; Paladin; Puralube; Refresh PM; Soothe XP; Stye; Tears Again; Tears Renewed; Throat Discs; Vagisil; Venez.: Agarol; Lacrimart; Mil-Par; Milcor†; Oleoderm.

White Soft Paraffin

905 (mineral hydrocarbons); Minkštasis baltas parafinas; Paraff. Moll. Alb.; Paraffinum Molle Album; Parafina blanda blanca; Valkovaseliini; Vaselin, vitt; Vaselina blanca; Vaselina Branca; Vaselina filante; Vaseline blanche; Vaseline Officinale; Vaselinum album; Vazelína bílá; Wazelina biała; White Petrolatum; White Petroleum

Белый Вазелин

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

Many pharmacopoeias use the title Vaselinum Album; in some countries the name 'Vaseline' is a trade-mark.

Ph. Eur. 6.2 (Paraffin, White Soft). Purified and wholly or nearly decolorised mixture of semi-solid hydrocarbons, obtained from petroleum. It may contain a suitable antoxidant. It is not suitable for oral use. A white or almost white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted. Drop point 35° to 70°. Practically insoluble in water, in alcohol, and in glycerol; slightly soluble in dichloromethane. Protect from light.

The BP 2008 gives White Petroleum Jelly as an approved syno-

USP 31 (White Petrolatum). A purified mixture of semisolid hydrocarbons obtained from petroleum, and wholly or nearly decolorised. It may contain a suitable stabiliser. A white or faintly yellowish unctuous mass, transparent in thin layers even after cooling to 0°. Insoluble in water; slightly soluble in cold or hot alcohol and in cold dehydrated alcohol; freely soluble in chloroform, in benzene, and in carbon disulfide; soluble in ether, in petroleum spirit, and in most fixed and volatile oils.

Yellow Soft Paraffin

Keltavaseliini: Minkštasis geltonas parafinas: Paraff, Moll. Flav.: Paraffinum Molle Flavum; Petrolatum; Petroleum Jelly; Sárga vazelin; Vaselin, gult; Vaselina Amarela; Vaselina amarilla; Vaselina filante amarilla; Vaseline jaune; Vaselinum flavum; Vazelína žlutá; Wazelina żółta; Yellow Petrolatum; Yellow Petroleum Jelly.

Жёлтый Вазелин

CAS - 8009-03-8

Pharmacopoeias. In Chin., Eur. (see p.vii), Int., Jpn, and US. Many pharmacopoeias use the title Vaselinum Flavum; in some countries the name 'Vaseline' is a trade-mark.

Ph. Eur. 6.2 (Paraffin, Yellow Soft). A purified mixture of semisolid hydrocarbons obtained from petroleum. A yellow, translucent, unctuous mass, slightly fluorescent in daylight when melted. It has a drop point of 40° to 60°. Practically insoluble in water, in alcohol, and in glycerol; slightly soluble in dichloromethane. Protect from light.

USP 31 (Petrolatum). A purified mixture of semi-solid hydrocarbons obtained from petroleum. It may contain a suitable stabiliser. It is an unctuous vellowish to light amber mass, having not more than a slight fluorescence even after being melted. It is transparent in thin layers. It is free or practically free from odour. M.p. 38° to 60°. Insoluble in water; practically insoluble in cold or hot alcohol and in cold dehydrated alcohol; freely soluble in benzene, in carbon disulfide, in chloroform, and in turpentine oil; soluble in ether, in petroleum spirit, and in most fixed and volatile oils

Adverse Effects

Adverse effects of soft paraffin are rare when used in topical preparations, but sensitivity reactions and acne have been reported after topical use. Granulomatous reactions after absorption or injection and lipoid pneumonia after aspiration have occurred.

Fire risk. Burns to the scalp, face, and hands have been reported1 in 5 patients who accidentally ignited their hair after the application of paraffin-based hair grease. Four patients suffered inhalation injury, 2 of whom required intubation. The death of a patient who, while smoking, ignited bandages covering a paraffin-based ointment for psoriasis,2 prompted the BNF to recommend that patients should be told not to smoke and to keep away from flames when using paraffin-based emollients.

- Bascom R, et al. Inhalation injury related to use of petrolatum-based hair grease. J Burn Care Rehabil 1984; 5: 327–30.
- National Patient Safety Agency. Skin treatment fire risk. Patient Safety Bulletin 2007 (Jan.); 4. Available at: http://www.npsa.nbs.uk/EasySiteWeb/GatewayLink.aspx?alId=6341 (accessed 29/08/08)

Hypersensitivity. The allergenicity of soft paraffin products has been investigated. 14 Considering their widespread use there are very few reports of sensitivity, 4 of nearly $80\,000$ patients patch tested with white soft paraffin, only 29 showed a positive reaction. White soft paraffin is generally less sensitising than yellow soft paraffin, although allergenicity differs from product to product. The allergenic components are probably polycyclic aromatic hydrocarbons present as impurities and quantities found in a particular paraffin depend on the source and purification method. Only the purest forms should be used in pharmaceuticals, cosmetics, and for patch testing, and highly purified white soft paraffin is preferred to yellow soft paraffin.

- 1. Dooms-Goossens A, Degreef H. Contact allergy to petrolatums (I). Sensitising capacity of different brands of yellow and white petrolatums. *Contact Dermatitis* 1983; **9:** 175–85.

 2. Dooms-Goossens A, Degreef H. Contact allergy to petrolatums
- (II). Attempts to identify the nature of the allergens. *Contact Dermatitis* 1983; **9:** 247–56.
- 3. Dooms-Goossens A, Dooms M. Contact allergy to petrolatums (III). Allergenicity prediction and pharmacopoeial requirements. *Contact Dermatitis* 1983; **9:** 352–9.
- 4. Schnuch A, et al. White petrolatum (Ph. Eur.) is virtually nonsensitizing: analysis of IVDK data on 80 000 patients tested be-tween 1992 and 2004 and short discussion of identification and designation of allergens. *Contact Dermatitis* 2006; **54**: 338–43.

Lipoid pneumonia. Various uses of soft paraffin have been associated with lipoid pneumonia, including topical facial use to treat psoriasis,1 long-term intranasal application for a dry nose,2 and use as a lubricant during nasogastric intubation.3

- Cohen MA, et al. Exogenous lipoid pneumonia caused by facial application of petrolatum. J Am Acad Dermatol 2003; 49: 1128–30.
- Brown AC, et al. Exogenous lipoid pneumonia due to nasal application of petroleum jelly. Chest 1994; 105: 968–9.
- 3. Bernabeu Mora R, et al. Neumonía lipoidea aguda debiba a la aspiratión accidental de vaselina utilizada en un sondaje na-sogástrico. Arch Bronconeumol 2000; **36:** 485-7.

Uses and Administration

Soft paraffin is used as an ointment basis and as an emollient in the management of skin disorders. It is not readily absorbed by the skin. Sterile dressings containing soft paraffin are used for wound dressing and as a packing material. Soft paraffin is also included in ointments used as ophthalmic lubricants in the management of dry eye (p.2140). Application of soft paraffin has been used for the eradication of pubic lice from the eyelashes (see Pediculosis, p.2034). It has been used as a contact medium to reduce pain during extracorporeal shock wave lithotripsy. Soft paraffin is also used in food manufacturing.