

Pharmacopoeias. In *Jpn.* Also in *USNF*.

USNF 26 (Polyoxyl 40 Stearate). A mixture of the mono- and di-esters of stearic acid and mixed macrogols, the average polymer length being about 40 oxyethylene units. It contains not less than 17% and not more than 27% of free macrogols. It is a waxy, white to light tan solid, odourless or with a faint fat-like odour. Congealing range 37° to 47°. Soluble in water, in alcohol, in acetone, and in ether; insoluble in liquid paraffin and in vegetable oils. Store in airtight containers.

Incompatibility. Macrogol stearates have been reported to be generally stable with electrolytes and weak acids or bases although strong acids or bases may cause hydrolysis and saponification. Discoloration or precipitation may occur with phenolic substances and complexation with preservatives. Decrease in the antimicrobial activity of bacitracin, chloramphenicol, phenoxymethylpenicillin, and tetracycline has been stated to occur with concentrations of macrogol stearates exceeding 5%.

Profile

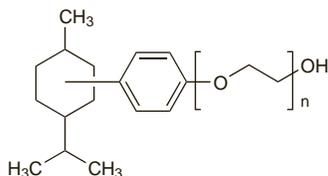
Macrogol stearates are macrogol esters that are used as emulsifying and solubilising agents.

Menfegol (rINN)

Menfégol; Menfegolum; Menpegol. α -[p-(p-Menthyl)phenyl]- ω -hydroxypoly(oxyethylene).

Менфегол

CAS — 57821-32-6.



Profile

Menfegol consists of menthylphenyl ethers of macrogols represented by the formula $C_{16}H_{23}(OCH_2CH_2)_nOH$. It is a nonionic surfactant used as a spermicide.

Adverse effects. Frequent use of menfegol in spermicidal foaming tablets has been associated with a high incidence of genital ulceration, which could increase the risk of infection by HIV.¹

- Goeman, J. *et al.* Frequent use of menfegol spermicidal vaginal foaming tablets associated with a high incidence of genital lesions. *J Infect Dis* 1995; **171**: 1611–14.

Preparations

Proprietary Preparations (details are given in Part 3)

Hong Kong: Neo Sampoo; **Malaysia:** Neo Sampoo; **Philipp.:** Neo Sampoo; **Singapore:** Neo Sampoo.

Mono- and Di-glycerides

E471 (mono- and di-glycerides of fatty acids); Mono y diglicerídicos.

Моно- и Диглицериды

Pharmacopoeias. In *USNF*.

USNF 26 (Mono- and Di-glycerides). A mixture of glycerol mono- and di-esters, with minor amounts of tri-esters, of fatty acids from edible oils. It contains not less than 40% of monoglycerides. It may contain suitable stabilisers. Store in airtight containers. Protect from light.

Profile

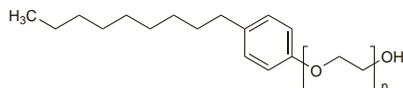
A mixture of mono- and di-glycerides is used as an emulsifying agent and food additive.

Nonoxinolins

Macrogol Nonylphenyl Ethers; Nonoxinolins; Nonoxynols. α -(4-Nonylphenyl)- ω -hydroxypoly(oxyethylene).

Ноноксинолы

CAS — 26027-38-3.



Nomenclature. Nonoxinolins are a series of nonylphenyl ethers of macrogols of differing chain lengths, represented by the formula $C_{15}H_{23}[O.CH_2.CH_2]_n.OH$. Nonoxinol is *BAN* and *rINN*. The name may be followed by a figure indicating the approximate number of oxyethylene groups in the polyoxyethylene chain. *USAN* specifies Nonoxynol 4, Nonoxynol 9, Nonoxynol 15, and Nonoxynol 30.

The symbol † denotes a preparation no longer actively marketed

Nonoxinol 9 (BAN, rINN)

Nonoxinol-9; Nonoxinol-9; Nonoxinolium 9; Nonoxynol 9 (*USAN*). α -(4-Nonylphenyl)- ω -hydroxynona(oxyethylene).

Ноноксинол 9

$C_{33}H_{60}O_{10}$ (nominal) = 616.8.

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

Ph. Eur. 6.2 (Nonoxinol 9). A mixture consisting mainly of monononylphenyl ethers of macrogols corresponding to the formula: $C_{15}H_{23}[O.CH_2.CH_2]_n.OH$ where the average value of *n* is 9. A clear, colourless to light yellow, viscous liquid. Miscible with water, with alcohol, and with vegetable oils. Store in airtight containers.

USP 31 (Nonoxynol 9). An anhydrous liquid mixture consisting chiefly of monononylphenyl ethers of macrogols corresponding to the formula $C_{15}H_{23}[O.CH_2.CH_2]_n.OH$, in which the average value of *n* is about 9. A clear, colourless to light yellow, viscous liquid. Soluble in water, in alcohol, and in maize oil. Store in airtight containers.

Nonoxinol 10 (BAN, rINN)

Nonoxinolium 10; Nonoxynol 10. α -(4-Nonylphenyl)- ω -hydroxydecyl(oxyethylene).

Ноноксинол 10

$C_{35}H_{64}O_{11}$ (nominal) = 660.9.

Nonoxinol 11 (BAN, rINN)

Nonoxinolium 11; Nonoxynol 11. α -(4-Nonylphenyl)- ω -hydroxyundecyl(oxyethylene).

Ноноксинол 11

$C_{37}H_{68}O_{12}$ (nominal) = 704.9.

Adverse Effects and Precautions

Nonoxinolins used as vaginal spermicides may cause local irritation.

Genito-urinary infections. Use of spermicidal foam or jelly containing nonoxinol 9 may disturb the normal vaginal flora and predispose to colonisation with *Escherichia coli* and the development of bacteriuria.¹ An increased risk of acute *E. coli* urinary-tract infection has been reported² associated with the use of condoms coated with nonoxinol 9. However, another study³ of women using nonoxinol-9 spermicidal contraceptives showed that most users experienced minimal disruption to the vaginal microbial ecosystem.

For reference to an increased incidence of some sexually transmitted diseases in women using nonoxinol 9, see Antimicrobial Activity, below.

- Hooton TM, *et al.* *Escherichia coli* bacteriuria and contraceptive method. *JAMA* 1991; **265**: 64–9.
- Fihn SD, *et al.* Association between use of spermicide-coated condoms and *Escherichia coli* urinary tract infection in young women. *Am J Epidemiol* 1996; **144**: 512–20.
- Schreiber CA, *et al.* Effects of long-term use of nonoxinol-9 on vaginal flora. *Obstet Gynecol* 2006; **107**: 136–43.

Pregnancy. Maternal use of spermicidal contraceptives has been linked to an increased frequency of congenital abnormalities, including trisomy, but it has been suggested that such studies may be flawed by recall bias.¹ Meta-analysis of 9 studies also supported the view that peri- and postconceptional maternal use of spermicides was not associated with adverse fetal outcome.²

- Mishell DR. Contraception. *N Engl J Med* 1989; **320**: 777–87.
- Einarson TR, *et al.* Maternal spermicide use and adverse reproductive outcome: a meta-analysis. *Am J Obstet Gynecol* 1990; **162**: 655–60.

Toxic shock syndrome. Toxic shock syndrome has been associated with the use of a vaginal contraceptive sponge impregnated with nonoxinol 9. A review¹ of 13 cases reported in the USA up to November 1984 found that in 4 of the cases there were other predisposing conditions: postpartum use, use during menstruation, and prolonged retention.

- Faich G, *et al.* Toxic shock syndrome and the vaginal contraceptive sponge. *JAMA* 1986; **255**: 216–18.

Uses

Nonoxinolins have surface active properties and may be used as solubilising agents. Nonoxinol 9 is used as a spermicide (see Contraception, p.2070).

Antimicrobial activity. Nonoxinol 9 has activity *in vitro* against a number of bacteria and viruses and it was hoped^{1,2} that use of spermicidal contraceptives containing nonoxinol 9 might provide some protection against sexually transmitted diseases, including chlamydial, gonococcal, and HIV infection. However, controlled studies involving HIV-negative female sex workers or other high-risk women have found that use of nonoxinol 9 does not reduce the rate of new HIV,^{3,4} or gonorrhoea or chlamydia infection;^{5,6} meta-analyses^{6,7} including these and other studies have come to similar conclusions. Furthermore, nonoxinol 9 has an irritant action and may increase the risk of genital ulceration, leading to an increased risk of infection by HIV. The United Nations,⁸ WHO,⁹ and FDA¹⁰ have therefore advised against its use by women at high risk.

- North BB. Vaginal contraceptives: effective protection from sexually transmitted diseases for women? *J Reprod Med* 1988; **33**: 307–311.

- Anonymous. Multipurpose spermicides. *Lancet* 1992; **340**: 211–13.
- Roddy RE, *et al.* A controlled trial of nonoxynol 9 film to reduce male-to-female transmission of sexually transmitted diseases. *N Engl J Med* 1998; **339**: 504–10.
- Van Damme L, *et al.* Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002; **360**: 971–7. Correction. *ibid.*; 1892.
- Roddy RE, *et al.* Effect of nonoxynol-9 gel on urogenital gonorrhoea and chlamydia infection: a randomized controlled trial. *JAMA* 2002; **287**: 1117–22.
- Wilkinson D, *et al.* Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men. Available in The Cochrane Database of Systematic Reviews; Issue 3. Chichester: John Wiley; 2002 (accessed 21/04/08).
- Wilkinson D, *et al.* Nonoxynol-9 for preventing vaginal acquisition of sexually transmitted infections by women from men. Available in The Cochrane Database of Systematic Reviews; Issue 1. Chichester: John Wiley; 2002 (accessed 21/04/08).
- Anonymous. UN warns against use of spermicide. *BMJ* 2000; **321**: 194.
- Anonymous. Nonoxinol 9 ineffective in preventing HIV infection. *WHO Drug Inf* 2002; **16**: 120–1.
- Food and Drug Administration. FDA mandates new warning for nonoxynol 9 OTC contraceptive products (issued 18/12/07). Available at: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01758.html> (accessed 21/04/08)

Preparations

Proprietary Preparations (details are given in Part 3)

Arg.: Delfen†; Lorphyn; **Austral.:** Lubarol; **Austria:** Delfen†; Patentex; **Braz.:** Pessarios Proflaticos Rendell†; Preserv Nonoxinol-9; **Canada.:** Advantage 24†; Delfen; Gynol II†; K-Y Plus Spermicidal Lubricant; Lifestyle; Ortho-Gynol; Rameses; Sheik; Shields†; Today; Trojan; VCF; **Chile:** Impidol; Supoviol; VCF†; **Cz.:** Delfen†; Patentex Oval N; **Fin.:** Patentex; **Ger.:** Patentex Oval; Patentex†; **Hong Kong:** Patentex; **Hung.:** Patentex; **India:** Delfen; **Ir.:** Patentex†; Gynol II†; Ortho-Creme; **Israel:** Delfen†; **Mex.:** Lorphyn; **NZ:** Lifestyle; Rendells Plus†; **Pol.:** Patentex Oval; Secural; **Port.:** Delfen†; Rendells; **Rus.:** Patentex Oval N (Патентекс Овал Н); **S.Afr.:** Delfen; Gynol II; **Spain:** Nacha†; **Swed.:** Gynol-Plus; **Switz.:** C-Film†; Delfen†; Patentex Oval N; Syn-A-Gen; **Turk.:** Lorphyn; **UK:** Delfen†; Duragel†; Gygel; Gynol II†; Ortho-Creme†; Orthoforms†; Prelude; **USA:** Advantage 24; Delfen; Encare; Gynol II; Semicid; Sheik Elite; Shur-Seal; Today; VCF.

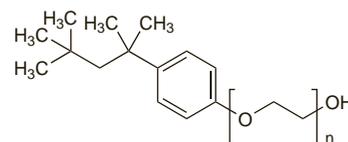
Multi-ingredient: **Arg.:** Methylate Iodopovidona; **Canada.:** Protectaid; **Ger.:** A-gen 53; **Hong Kong:** Protectaid; **Israel:** Glovan; **Mex.:** Nor-forms†; Sin-A-Gen; **Spain:** Lavolen; **Turk.:** Agen; **UK:** Protectaid.

Octoxinolins

Macrogol Tetramethylbutylphenyl Ethers; Octoxinolins; Octoxynols; Octylphenoxy Polyethoxyethanol. α -(4-(1,1,3,3-Tetramethylbutyl)phenyl)- ω -hydroxypoly(oxyethylene).

ОКТОКСИНОЛЫ

CAS — 9002-93-1.



Nomenclature. Octoxinolins are a series of tetramethylbutylphenyl ethers of macrogols of differing chain lengths, represented by the formula $C_{14}H_{21}[O.CH_2.CH_2]_n.OH$.

Octoxinol is *BAN* and *rINN*. The name may be followed by a figure indicating the approximate number of oxyethylene groups in the polyoxyethylene chain. *USAN* specifies Octoxynol 9.

The name p-di-isobutyl-phenoxypolyethoxyethanol has been used to describe octoxinol 9 but may have also been applied to other octoxinolins.

Octoxinol 9 (BAN, rINN)

Octoxinolium 9; Octoxynol 9 (*USAN*).

ОКТОКСИНОЛ 9

$C_{32}H_{58}O_{10}$ (nominal) = 602.8.

Pharmacopoeias. In *USNF*.

USNF 26 (Octoxynol 9). An anhydrous liquid mixture consisting chiefly of mono-octylphenyl ethers of macrogols, corresponding to the formula $C_{14}H_{21}[O.CH_2.CH_2]_n.OH$, in which the average value of *n* is about 9. A clear, pale yellow, viscous liquid with a faint odour. Miscible with water, with alcohol, and with acetone; soluble in toluene and in benzene; practically insoluble in petroleum spirit. Store in airtight containers.

Octoxinol 10 (BAN, rINN)

Octoxinolium 10; Oktoksinoli-10; Oktoksinolis 10; Oktoksynol 10; Oktoxinol-10; Oktoxinol 10.

ОКТОКСИНОЛ 10

$C_{34}H_{62}O_{11}$ (nominal) = 646.8.

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

Ph. Eur. 6.2 (Octoxinol 10). A mixture consisting mainly of mono-octylphenyl ethers of macrogols corresponding to the formula: $C_{14}H_{21}[O.CH_2.CH_2]_n.OH$ where the average value of *n* is

10. A clear, colourless or light yellow, viscous liquid. Miscible with water, with alcohol, and with vegetable oils. Store in airtight containers.

Profile

Octoxinols have surface active properties and may be used as solubilising agents. They are also used as spermicides.

Preparations

Proprietary Preparations (details are given in Part 3)

Austral.: Ortho-Gynol; **NZ:** Ortho-Gynol; **USA:** Ortho-Gynol†.

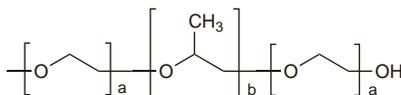
Multi-ingredient: **Austral.:** Summers Eve Feminine; **Chile:** Summer's Eve Hierbas†.

Poloxamers

Polioxietilen-propilenglicol; Poloksamerit; Poloksamerai; Poloxamera; Poloxamerek; Poloxamerer; Poloxamères; Poloxameros; Poloxamery; Polyethylene-polypropylene glycol. α -Hydro- ω -hydroxy poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) block copolymer.

Полюксамеры

CAS — 9003-11-6.



Nomenclature. Poloxamer is *BAN* and *rINN*. The name is followed by a figure, the first 2 digits of which, when multiplied by 100, correspond to the approximate average molecular weight of the polyoxypropylene portion and the third digit, when multiplied by 10, corresponds to the percentage by weight of the polyoxyethylene portion. *USAN* specifies Poloxamer 182D, Poloxamer 182LF, Poloxamer 188, Poloxamer 188LF, and Poloxamer 331.

Poloxalene (*BAN*, *USAN*, *rINN*) is also a poloxamer.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Poloxamers). A synthetic block copolymer of ethylene oxide and propylene oxide represented by the general formula: $\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_c\text{H}$. It may contain a suitable antioxidant. Poloxamer 124 is a colourless or almost colourless liquid. Poloxamer 237 and poloxamer 338 are white or almost white, waxy powders, microbeads or flakes; m.p. about 50°. Poloxamers 124, 237, and 338 are very soluble in water and in alcohol; practically insoluble in petroleum spirit (50° to 70°). pH of a 10% solution in water is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). A synthetic block copolymer of ethylene oxide and propylene oxide with the general formula $\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_c\text{H}$. It may contain a suitable antioxidant. Poloxamer 124 is a colourless liquid with a mild odour. Poloxamers 237 and 338 are white, prilled or cast solids, odourless or with a mild odour. All poloxamers are freely soluble in water and in alcohol. Poloxamer 124 is freely soluble in isopropyl alcohol and in propylene glycol; poloxamer 237 is sparingly soluble in isopropyl alcohol and in xylene; poloxamer 338 is sparingly soluble in propylene glycol; poloxamer 124 is freely soluble in xylene. A 2.5% solution in water has a pH of 5.0 to 7.5. Store in airtight containers.

Incompatibility. Poloxamers have been reported to be incompatible with hydroxybenzoates and phenols.

Poloxalene (*BAN*, *USAN*, *rINN*)

Poloxalène; Poloxaleno; Poloxalenum; SKF-18667.

Полюксален

CAS — 9003-11-6.

Pharmacopoeias. In *US* for veterinary use only.

USP 31 (Poloxalene). A synthetic block copolymer of ethylene oxide and propylene oxide. A colourless or pale yellow liquid. Soluble in water, in chloroform, and in ethylene dichloride. A 2.5% solution in water has a pH of 5.0 to 7.5. Store in airtight containers at a temperature of 8° to 15°. Protect from light.

Poloxamer 188 (*BAN*, *USAN*, *rINN*)

Poloxalkol; Poloxamère 188; Poloxámero 188; Poloxamerum 188.

Полюксамер 188

NOTE. Compounded preparations of poloxamer 188 may be represented by the following names:

- Co-danthramer *x/y* (*BAN*)—where *x* and *y* are the strengths in milligrams of dantron and poloxamer respectively.

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Poloxamers). Poloxamer 188 is a poloxamer in which *a* in the general formula given above is 75 to 85 and *b* is 25 to 30; it has an average molecular weight of 7680 to 9510. It is a white or almost white, waxy powder, microbeads, or flakes. M.p. about 50°. Very soluble in water and in alcohol; practically

insoluble in petroleum spirit (50° to 70°). pH of a 10% solution is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). Poloxamer 118 is a poloxamer in which *a* in the general formula averages 80 and *b* averages 27; it has an average molecular weight of 7680 to 9510. A white prilled or cast solid, odourless or with a very mild odour. M.p. about 52°. Freely soluble in water and in alcohol. Store in airtight containers.

Poloxamer 407 (*BAN*, *rINN*)

Poloxamère 407; Poloxámero 407; Poloxamerum 407.

Полюксамер 407

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF*.

Ph. Eur. 6.2 (Poloxamers). Poloxamer 407 is a poloxamer in which *a* in the general formula given above is 95 to 105 and *b* is 54 to 60; it has an average molecular weight of 9840 to 14 600. It is a white or almost white, waxy powder, microbeads, or flakes. M.p. about 50°. Very soluble in water and in alcohol; practically insoluble in petroleum spirit (50° to 70°). pH of a 10% solution in water is 5.0 to 7.5. Store in airtight containers.

USNF 26 (Poloxamer). Poloxamer 407 is a poloxamer in which *a* in the general formula averages 101 and *b* averages 56; it has an average molecular weight of 9840 to 14 600. A white, prilled or cast solid, odourless or with a very mild odour. M.p. about 56°. Freely soluble in water, in alcohol, and in isopropyl alcohol. Store in airtight containers.

Precautions

Poloxamers may increase the absorption of liquid paraffin and other fat-soluble substances.

Uses and Administration

Poloxamers are used as emulsifying agents for intravenous fat emulsions, as solubilising agents to maintain clarity in elixirs and syrups, and as wetting agents for antibacterials. They may also be used in ointment or suppository bases and as tablet binders or coaters.

Poloxamer 188 is used as a wetting agent in the treatment of constipation. It is usually given with a laxative such as dantron. It has also been used as an emulsifying agent in fluorocarbon blood substitutes. Poloxamer 188 has been investigated for its ability to improve blood flow in sickle-cell crisis; it has also been tried in myocardial infarction. Other investigational uses include the treatment of burn.

Poloxamer 407 is used in solutions for contact lens care, as is poloxamer 338.

Poloxalene is used as a defoaming agent in the treatment of bloat in ruminants.

References

1. Orringer EP, *et al.* Purified poloxamer 188 for treatment of acute vaso-occlusive crisis of sickle cell disease: a randomized controlled trial. *JAMA* 2001; **286**: 2099–2106.
2. Gibbs WJ, Hagemann TM. Purified poloxamer 188 for sickle cell vaso-occlusive crisis. *Ann Pharmacother* 2004; **38**: 320–4.
3. Dumortier G, *et al.* A review of poloxamer 407 pharmaceutical and pharmacological characteristics. *Pharm Res* 2006; **23**: 2709–28.

Preparations

Proprietary Preparations (details are given in Part 3)

Austral.: Coloxyl; Pliagel†; **Canad.:** Clerz†; **Fr.:** Alkenide†; **NZ:** Coloxyl; **S.Afr.:** Pliagel.

Multi-ingredient: **IrL:** Ailax; Codalax; Cotron; **NZ:** Codalax†; Conthram†; **Thai:** Siduol; **UK:** Ailax†; Codalax; Danlac; **USA:** Baby Orajel Tooth and Gum Cleanser; ControlRx.

Polyoxyl Castor Oils

Aceites de ricino polioxietilenados; Macroglylycerol Ricinoleate; Macroglycérol, ricinoléate de; Macroglycérolol ricinoleas; Makrogol-glicerín-éter-ricinoléat; Makroglycérolol ricinoleatas; Makroglycérololricinoléat; Makroglycérololricinoléaatti; Makroglycérolol ricinoleatin; Polyethoxylated Castor Oils; Polyoxyethylene Castor Oils.

Полиэтиленгликоля Касторовые Масла

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

Ph. Eur. 6.2 (Macroglylycerol Ricinoleate; Polyoxyl Castor Oil BP 2008). It contains mainly ricinoleyl glycerol ethoxylated with 30 to 50 molecules of ethylene oxide (nominal value), with small amounts of macrogol ricinoleate and of the corresponding free glycols. It results from the reaction of castor oil with ethylene oxide. A clear, yellow, viscous liquid or semi-solid. Relative density about 1.05; viscosity, at 25°, 500 to 800 mPa s. Freely soluble in water and in alcohol; very soluble in dichloromethane. Protect from light.

Polyoxyl 35 Castor Oil

Aceite de ricino polioxil 35.

Полиэтиленгликоля 35 Касторовое Масло

Pharmacopoeias. In *USNF*.

USNF 26 (Polyoxyl 35 Castor Oil). A mixture of the tri-ricinoleate ester of ethoxylated glycerol with smaller amounts of macrogol ricinoleate and the corresponding free glycols. It is

produced by reacting 1 mole of glycerol ricinoleate with about 35 moles of ethylene oxide.

A yellow oily liquid with a faint characteristic odour. Sp. gr. 1.05 to 1.06; viscosity, at 25°, 650 to 850 mPa s. Very soluble in water, producing a practically odourless and colourless solution; soluble in alcohol and in ethyl acetate; insoluble in mineral oils. Store in airtight containers.

Incompatibility. Polyoxyl castor oils are reported to affect polyvinyl chloride containers and apparatus adversely.

Adverse Effects

Polyoxyl castor oils (such as *Cremophor EL*) used as vehicles in intravenous injections have been associated with severe anaphylactoid reactions, hyperlipidaemias, alterations in blood viscosity, and erythrocyte aggregation. They may also lead to adverse effects due to alterations in the pharmacokinetics of the formulated drug.

References

1. Bagnarello AG, *et al.* Unusual serum lipoprotein abnormality induced by the vehicle of miconazole. *N Engl J Med* 1977; **296**: 497–9.
2. Forrest ARW, *et al.* Long-term Althesin infusion and hyperlipidaemia. *BMJ* 1977; **2**: 1357–8.
3. Dye D, Watkins J. Suspected anaphylactic reaction to Cremophor EL. *BMJ* 1980; **280**: 1353.
4. Howrie DL, *et al.* Anaphylactoid reactions associated with parenteral cyclosporine use: possible role of Cremophor EL. *Drug Intell Clin Pharm* 1985; **19**: 425–7.
5. Chapuis B, *et al.* Anaphylactic reaction to intravenous cyclosporine. *N Engl J Med* 1985; **312**: 1259.
6. Siddall SJ, *et al.* Anaphylactic reactions to teniposide. *Lancet* 1989; **i**: 394.
7. ten Tije AJ, *et al.* Pharmacological effects of formulation vehicles: implications for cancer chemotherapy. *Clin Pharmacokinet* 2003; **42**: 665–85.
8. Hennenfent KL, Govindan R. Novel formulations of taxanes: a review. Old wine in a new bottle? *Ann Oncol* 2006; **17**: 735–49.

Uses

Polyoxyl castor oils are macrogol esters used as emulsifying and solubilising agents. Polyoxyl 35 castor oil has been used as a solvent in vehicles for various intravenous injections.

Polyoxyl Hydrogenated Castor Oils

Aceites de ricino hidrogenados y polioxietilenados; Macroglylycerol Hydroxystearate; Macroglycérol, hydroxystéarate de; Macroglycérolol hydroxystearas; Makrogol-glicerín-éter-hydroxysztearát; Makroglycérolol hidrokissteratas; Makroglycérolol hydroxystearat; Makroglycérololhidrokissteaaraatti.

Полиэтиленгликоля Касторовые Масла

Гидрогенизированные

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

Ph. Eur. 6.2 (Macroglylycerol Hydroxystearate; Hydrogenated Polyoxyl Castor Oil BP 2008). It contains mainly trihydroxystearyl glycerol ethoxylated with 7 to 60 molecules of ethylene oxide (nominal value), with small amounts of macrogol hydroxystearate and of the corresponding free glycols. It results from the reaction of hydrogenated castor oil with ethylene oxide. Polyoxyl hydrogenated castor oil with less than 10 units of ethylene oxide per molecule is a yellowish, turbid, viscous liquid. Practically insoluble in water; dispersible in alcohol; soluble in acetone. Polyoxyl hydrogenated castor oil with more than 20 units of ethylene oxide per molecule is a white or yellowish, semi-liquid or pasty mass. Freely soluble in water, in alcohol, and in acetone; practically insoluble in petroleum spirit.

Polyoxyl 40 Hydrogenated Castor Oil

Aceite de ricino hidrogenado polioxil 40.

Полиэтиленгликоля 40 Касторовое Масло

Гидрогенизированное

Pharmacopoeias. In *USNF*.

USNF 26 (Polyoxyl 40 Hydrogenated Castor Oil). A mixture of mainly the trihydroxystearate ester of ethoxylated glycerol, with smaller amounts of macrogol trihydroxystearate and the corresponding free glycols. It is produced by reacting 1 mole of glycerol trihydroxystearate with about 40 to 45 moles of ethylene oxide.

A white to yellowish paste or pasty liquid with a faint odour. Congealing range 20° to 30°. Very soluble in water, producing an odourless, colourless solution; soluble in alcohol and in ethyl acetate; insoluble in liquid paraffin. Store in airtight containers.

Profile

Polyoxyl hydrogenated castor oils are used as surfactants.

Polysorbates

Polisorbatos.

Полисорбаты

Description. A series of mixtures of fatty acid esters of sorbitol and its anhydrides copolymerised with about 20 moles of ethylene oxide for each mole of sorbitol and its anhydrides.