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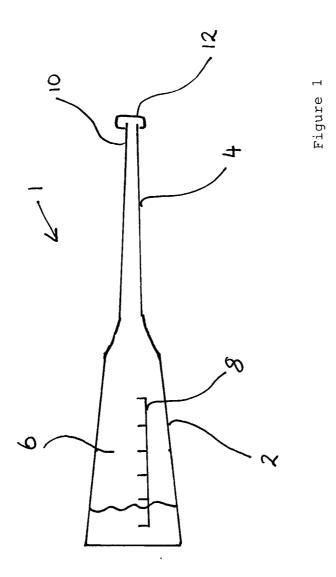
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(54) Abstract Title: Lubricant

(57) A lubricant comprising 20-50% water, 30-50% alkylene glycol, such as propylene glycol, and 7-21% glyceryl polymer, such as glyceryl polymethacrylate. The lubricant may comprise an aloe compound such as aloe vera. The lubricant may comprise one or more tocopherol and/or tocotrienol compounds. The lubricant is for alleviating vaginal dryness. Also disclosed is a delivery device for administering the lubricant and the delivery device is preferably disposable.



5 Lubricant

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The present invention relates to a lubricant, a delivery device for a lubricant, a lubricant for treating vaginal dryness, at all ages and especially in menopausal and post menopausal women, the use of a lubricant for the manufacture of a medicament for the treatment of vaginal dryness and a method for the treatment of symptoms of vaginal dryness.

Vaginal dryness is common in women of all ages but is

15 particularly prevalent in menopausal and postmenopausal women.

The main causes include, impaired sexual arousal, oestrogen deficiency, disease, trauma, pelvic radiotherapy and the effect of some drugs.

- Vaginal dryness can present either as a basal dryness which can give rise to symptoms such as vulval soreness and irritation, or as a dryness during sexual arousal, precluding comfortable penile vaginal penetration during intercourse.
- 25 At present a treatment for vaginal dryness in postmenopausal women, when oestrogen levels are low, is oestrogen replacement therapy. Although oestrogen therapy is generally believed to be safe in the short term, some women have reservations about embarking on such treatments and so lubricants are often used 30 during sexual activity as an alternative. Even for those women who are happy to rely on hormone treatment, it can take up to three months before any beneficial effects are noted. meantime these women are advised to use a lubricant to treat their vaginal dryness. Furthermore, when oestrogen replacement 35 is discontinued, vaginal dryness can recur causing painful or uncomfortable sexual activity which can be relieved by the use of a lubricant.

5 The present invention provides a lubricant, which can be applied to the vagina to reduce dryness. The lubricant is most preferably for use prior to or during sexual activity.

According to a first aspect of the present invention there is provided a lubricant comprising from 20 to 50% water, from 30 to 50% of an alkylene glycol and from 7 to 21 % of a glyceryl polmer.

This lubricant can be advantageous over currently available 15 lubricants because the relative amounts of the constituent ingredients result in a lubricant, which has an improved consistency over conventional lubricants. In particular the consistency may allow the lubricant to remain at the locality at which it is placed for a longer period of time than seen with 20 conventional lubricants. In particular the lubricant when applied to the inside of the vagina, may stay inside the vagina for a longer period of time than seen with conventional lubricants. This advantageously allows the lubricant to be applied in privacy well before intercourse. Any leakage of the 25 lubricant may provide lubrication of the vulva during foreplay thereby relieving discomfort due to dryness during clitoral stimulation by any means.

Preferably the lubricant comprises from 25 to 45% water, more 30 preferably from 30 to 40% water, and most preferably 33.87% water.

Ideally the lubricant comprises from 32 to 48% of an alkylene glycol, more preferably from 34 to 46% of an alkylene glycol,

35 more preferably 36 to 44% of an alkylene glycol, more preferably 38 to 42% of an alkylene glycol, and most preferably comprises 41.83% of an alkylene glycol. Ideally the alkylene glycol is propylene glycol.

of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 9 to 19% of a glyceryl polmer, in a more preferred embodiment, in a more preferred embodiment the lubricant comprises from 10 to 17% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 11 to 15% of a glyceryl polmer, in a more preferred embodiment, in a more preferred embodiment the lubricant comprises from 12 to 14% of a glyceryl polmer, in a most preferred embodiment the lubricant comprises 13.65% of a glyceryl polmer. Ideally the glyceryl polmer is glyceryl polmethacrylate.

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The lubricant advantageously has a viscosity which allows it to be placed inside the vagina providing internal lubrication. This advantageously allows the lubricant to be applied in privacy well before intercourse. Any leakage of the lubricant may provide lubrication of the vulva during foreplay thereby relieving discomfort due to dryness during clitoral stimulation by any means.

Ideally at least some of the lubricant when applied to the

vagina will remain inside the vagina for up to 36 hours.

However more preferably the viscosity is such that at least some of the lubricant will remain in place inside the vagina for up to 24 hours, more preferably for up to 12 hours and most preferably for up to 6 hours. This effect can be achieved without the inclusion of adhesives in the lubricant. Most preferably the amount of lubricant, which remains inside the vagina during use, is enough to provide adequate lubrication for sexual intercourse. Preferably from 20% to 100% remains inside the vagina, more preferably from 40% to 100%, more preferably from 60% to 95%, and most preferably from 80% to 90%.

The lubricant most preferably has a viscosity of from 12,000 cps to 17,000 cps, more preferably, from 13,000 cps to 16,000 cps, more preferably from 14,000 cps to 15,000 cps and most preferably 14,360 cps. Ideally the lubricant's viscosity is

5 measured at 20°C. Preferably the viscosity is stable. Most preferably the viscosity does not vary more than 2.5% over 6 weeks but more preferably over 12 weeks.

The lubricant also preferably includes one or more tocopherol and/or tocotrienol compounds (vitamin E), most preferably a mix of tocopherols. Ideally the lubricant may comprise an aloe compound for example aloe vera. The addition of either or both of these substances can result in a lubricant, which has properties that encourage cell regeneration.

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The lubricant may also comprise one or more of the following compounds: A preservative (for example methylparaben, propylparaben or potassium sorbate), a compound to solubilise any oily/ insoluable components (for example, PEG-40

hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26 and trideceth-9), a gelling agent (for example, xanthan gum, or a cellulose for example, methylcellulose, hydroxyethylcellulose,

hyroxypropylmethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose) and/or a PVM/MA copolymer.

A second aspect of the present invention provides a lubricant comprising one or more tocopherol and/or tocotrienol compounds (for example a commercially available vitamin E compound), most preferably a mix of tocopherols. The addition of vitamin E to a lubricant may provide a product which encourages cell regeneration in addition to its lubrication qualities.

Preferred features of this second aspect of the invention may be as described above in connection with the first aspect.

In particular the lubricant may further comprise one or more of water, an alkylene glycol and a glyceryl polmer. Preferably the lubricant comprises water, an alkylene glycol and a glyceryl polmer. Ideally the lubricant comprises from 20 to 50% water,

5 from 30 to 50% of an alkylene glycol and from 7 to 21 % of a glyceryl polmer.

Preferably the lubricant comprises from 25 to 45% water, more preferably from 30 to 40% water and most preferably 33.87% water.

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Ideally the lubricant comprises from 32 to 48% of an alkylene glycol, more preferably from 34 to 46% of an alkylene glycol, more preferably 36 to 44% of an alkylene glycol, more preferably 38 to 42% of an alkylene glycol, and most preferably comprises 41.83% of an alkylene glycol. Ideally the alkylene glycol is propylene glycol.

In a preferred embodiment the lubricant comprises from 7 to 21 % of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 9 to 19% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 10 to 17% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 11 to 15% of a glyceryl polmer, in a more preferred embodiment, in a more preferred embodiment the lubricant comprises from 12 to 14% of a glyceryl polmer, in a most preferred embodiment the lubricant comprises 13.65% of a glyceryl polmer. Ideally the glyceryl polmer is glyceryl polmethacrylate.

30. The lubricant advantageously has a viscosity which allows it to be placed inside the vagina providing internal lubrication. This advantageously allows the lubricant to be applied in privacy well before intercourse. Any leakage of the lubricant may provide lubrication of the vulva during foreplay thereby relieving discomfort due to dryness during clitoral stimulation by any means. This effect may be achieved without the inclusion of adhesives in the lubricant.

Ideally at least some of the lubricant when applied to the vagina will remain inside the vagina for up to 36 hours.

However more preferably the viscosity is such that at least some of the lubricant will remain in place inside the vagina for up to 24 hours, more preferably for up to 12 hours and most preferably for up to 6 hours. Most preferably the amount of lubricant, which remains inside the vagina during use, is enough to provide adequate lubrication for sexual intercourse.

Preferably from 20% to 100% remains inside the vagina, more preferably from 40% to 100%, more preferably from 60% to 95%, and most preferably from 80% to 90%.

The lubricant most preferably has a viscosity of from 12,000 cps to 17,000 cps, more preferably, from 13,000 cps to 16,000 cps, more preferably from 14,000 cps to 15,000 cps and most preferably 14,360 cps. Ideally the lubricant's viscosity is measured at 20°C. Preferably the viscosity is stable. Most preferably the viscosity does not vary more than 2.5% over 6 weeks but more preferably over 12 weeks.

Ideally the lubricant may also further comprise an aloe compound for example aloe vera.

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The lubricant may also comprise one or more of the following compounds: A preservative (for example methylparaben, propylparaben or potassium sorbate), a compound to solubilise any oily/ insoluable components (for example, PEG-40

hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26 and trideceth-9), a gelling agent (for example, xanthan gum, or a cellulose for example, methylcellulose, hydroxyethylcellulose,

hyroxypropylmethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose) and/or a PVM/MA copolymer.

A third aspect of the present invention proves a lubricant comprising an aloe compound for example aloe vera. The addition of aloe vera to a lubricant can provide a product which may

5 encourage cell regeneration in addition to its lubrication qualities.

Preferred features of this third aspect of the invention may be as described above in connection with the first and second aspects.

In particular the lubricant may further comprise one or more of water, an alkylene glycol and a glyceryl polmer. Ideally the lubricant comprises water, an alkylene glycol and a glyceryl polmer. Ideally the lubricant comprises from 20 to 50% water, from 30 to 50% of an alkylene glycol and from 7 to 21% of a glyceryl polmer.

Preferably the lubricant comprises from 25 to 45% water, more 20 preferably from 30 to 40% water and most preferably 33.87% water.

Ideally the lubricant comprises from 32 to 48% of an alkylene glycol, more preferably from 34 to 46% of an alkylene glycol,

25 more preferably 36 to 44% of an alkylene glycol, more preferably 38 to 42% of an alkylene glycol, and most preferably comprises 41.83% of an alkylene glycol. Ideally the alkylene glycol is propylene glycol.

30 In a preferred embodiment the lubricant comprises from 7 to 21 % of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 9 to 19% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 10 to 17% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 11 to 15% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 12 to 14% of a glyceryl polmer, in a most preferred embodiment the lubricant comprises 13.65% of a glyceryl polmer. Ideally the glyceryl polmer is glyceryl polmethacrylate.

5 The lubricant advantageously has a viscosity which allows it to be placed inside the vagina providing internal lubrication.

This advantageously allows the lubricant to be applied in privacy well before intercourse. Any leakage of the lubricant may provide lubrication of the vulva during foreplay thereby

10 relieving discomfort due to dryness during clitoral stimulation by any means. This effect can be achieved without the inclusion of adhesives in the lubricant.

Ideally at least some of the lubricant when applied to the
vagina will remain inside the vagina for up to 36 hours.
However more preferably the viscosity is such that at least some of the lubricant will remain in place inside the vagina for up to 24 hours, more preferably for up to 12 hours and most preferably for up to 6 hours. Most preferably the amount of lubricant, which remains inside the vagina during use, is enough to provide adequate lubrication for sexual intercourse.

Preferably from 20% to 100% remains inside the vagina, more preferably from 40% to 100%, more preferably from 60% to 95%, and most preferably from 80% to 90%.

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The lubricant most preferably has a viscosity of from 12,000 cps to 17,000 cps, more preferably, from 13,000 cps to 16,000 cps, more preferably from 14,000 cps to 15,000 cps and most preferably 14,360 cps. Ideally the lubricant's viscosity is measured at 20°C. Preferably the viscosity is stable. Most preferably the viscosity does not vary more than 2.5% over 6 weeks but more preferably over 12 weeks.

Ideally the lubricant may also further comprise one or more tocopherol and/or tocotrienol compounds (for example commercially available vitamin E), most preferably a mix of tocopherols.

The lubricant may also comprise one or more of the following 40 compounds: A preservative (for example methylparaben,

propylparaben or potassium sorbate), a compound to solubilise any oily/ insoluable components (for example, PEG-40 hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26 and trideceth-9), a gelling agent (for example, xanthan gum, or a cellulose for example, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and sodium

carboxymethylcellulose) and/or a PVM/MA copolymer.

A fourth aspect of the present invention proves a lubricant

having a viscosity of from 12,000 cps to 17,000 cps. This
viscosity advantageously may allow the lubricant to be placed
inside the vagina providing internal lubrication. This
advantageously allows the lubricant to be applied in privacy
well before intercourse. Any leakage of the lubricant may

provide lubrication of the vulva during foreplay thereby
relieving discomfort due to dryness during clitoral stimulation
by any means. This effect may be achieved without the inclusion
of adhesives in the lubricant.

Ideally at least some of the lubricant when applied to the vagina will remain inside the vagina for up to 36 hours. However more preferably the viscosity is such that at least some of the lubricant will remain in place inside the vagina for up to 24 hours, more preferably for up to 12 hours and most preferably for up to 6 hours. Most preferably the amount of lubricant, which remains inside the vagina during use, is enough to provide adequate lubrication for sexual intercourse. Preferably from 20% to 100% remains inside the vagina, more preferably from 40% to 100%, more preferably from 60% to 95%, and most preferably from 80% to 90%.

Preferred features of this fourth aspect of the invention may be as described above in connection with the first, second and third aspects.

In a preferred embodiment the lubricant has a viscosity of from 13,000 cps to 16,000 cps, more preferably from 14,000 cps to 15,000 cps and most preferably 14,360 cps. Ideally the lubricant's viscosity is measured at 20°C. Preferably the viscosity is stable. Most preferably the viscosity does not vary more than 2.5% over 6 weeks but more preferably over 12 weeks.

To help achieve a desired consistency the lubricant preferably comprises from 20 to 50% water, from 30 to 50% of an alkylene glycol and from 7 to 21 % of a glyceryl polmer.

In a preferred embodiment the lubricant comprises from 25 to 45% water, more preferably from 30 to 40% water, and most preferably 33.87% water.

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Ideally the lubricant comprises from 32 to 48% of an alkylene glycol, more preferably from 34 to 46% of an alkylene glycol, more preferably 36 to 44% of an alkylene glycol, more preferably 38 to 42% of an alkylene glycol, and most preferably comprises 41.83% of an alkylene glycol. Ideally the alkylene glycol is propylene glycol.

In a preferred embodiment the lubricant comprises from 7 to 21 % of a glyceryl polmer, in a more preferred embodiment the

- lubricant comprises from 9 to 19% of a glyceryl polmer, in a . more preferred embodiment the lubricant comprises from 10 to 17% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 11 to 15% of a glyceryl polmer, in a more preferred embodiment the lubricant comprises from 12 to 14%
- of a glyceryl polmer, in a most preferred embodiment the lubricant comprises 13.65% of a glyceryl polmer. Ideally the glyceryl polmer is glyceryl polmethacrylate.

Ideally the lubricant may also further comprise one or more tocopherol and/or tocotrienol compounds (vitamin E), most

5 preferably a mix of tocopherols. The lubricant may comprise an aloe compound for example aloe vera.

The lubricant may also comprise one or more of the following compounds: A preservative (for example methylparaben,

- propylparaben or potassium sorbate), a compound to solubilise any oily/ insoluable components (for example, PEG-40 hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26 and trideceth-9), a gelling agent (for example, xanthan gum, or a cellulose for example,
- 15 methylcellulose, hydroxyethylcellulose, hyroxypropylmethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose) and/or a PVM/MA copolymer.
- Presently available lubricants are normally contained within a 20 tube. When the lubricant is needed a small amount is squeezed from the tube onto a user's finger or fingers. The lubricant is then manually applied to the external genital area by the user.

Thus lubricant is not typically applied to the inside of the vagina where it is most needed to aid penetration.

Therefore a fifth aspect of the present invention provides a delivery device for a lubricant comprising a squeezable container having an elongate dispensing nozzle, wherein the dispensing nozzle is from 20mm to 65mm in length.

This dispensing device is advantageous as it can allow a lubricant contained within it to be dispensed directly into the vagina where it is most needed. The dispensing nozzle is preferably from 30mm to 65mm in length, more preferably from 40mm to 60mm, and most preferably 55mm in length. Ideally the delivery device contains a lubricant. Preferably the lubricant is as described in connection with the first, second, third and/or fourth aspects of this invention.

In a preferred embodiment the container is opaque, transparent or translucent such that when it is charged with a lubricant, the volume of lubricant held within it can be seen. This is advantageous, as it can allow a user to control the amount of lubricant dispensed. Providing a volume indicator on the container can further enhance this advantage.

The container and/or the dispensing nozzle is preferably made from a plastics material, for example polyethylene, polyvinyl chloride, ABS, polypropylene, polycarbonate, nylon, acrylic or a composite of 2 or more plastics.

In a preferred embodiment the delivery device is sized for containing a single dose of lubricant and is most preferably disposable. Ideally the delivery device contains from 2ml to 20ml of lubricant, more preferably of from 3ml to 15ml of lubricant, more preferably of from 4ml to 10ml of lubricant and most preferably 5ml of lubricant. This volume has been found to provide adequate lubrication for a single use.

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A sixth aspect of the present invention provides a delivery device for a lubricant comprising a squeezable container having an elongate dispensing nozzle, wherein the container is at least partially opaque, transparent or translucent, for example to allow a user to gauge how much lubricant is left inside the delivery device. Preferably the delivery device is as described in connection with the fifth aspect of this invention.

Ideally the delivery device further contains a lubricant.

Preferably the lubricant is as described in connection with the

first, second, third and/or fourth aspects of this invention.

As stated above the opaque, transparent or translucent nature of the container means that when it is charged with a lubricant, the volume of the lubricant can be seen. This is advantageous, as it can allow a user to control the amount of lubricant 5 dispensed. Providing a volume indicator on the container, indicating volume can further enhance this advantage

In a preferred embodiment the dispensing nozzle is from 20mm to 65mm in length, more preferably from 30mm to 65mm in length, more preferably from 40mm to 60mm, and most preferably 55mm in length.

In a preferred embodiment the delivery device is sized for containing a single dose of lubricant and is most preferably disposable. Ideally the delivery device contains from 2ml to 20ml of lubricant, more preferably of from 3ml to 15ml of lubricant, more preferably of from 4ml to 10ml of lubricant and most preferably 5ml of lubricant. This volume has been found to provide adequate lubrication.

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In a seventh aspect of the present invention there is provided a lubricant for use in treating vaginal dryness.

In an eighth aspect of the present invention there is provided

25 the use of a vaginal lubricant for the manufacture of a

medicament for the treatment of vaginal dryness. The medicament

preferably being presented as a dosage form in a delivery device
as defined above.

30 In a ninth aspect of the present invention there is provided a method for the treatment of symptoms of vaginal dryness, comprising introducing into a vagina a lubricant as described above in relation to the first, second, third and/or fourth aspects of the present invention. Most preferably the lubricant is introduced into the vagina using a delivery device as described in accordance with the fifth and/or sixth aspects of the present invention. Preferably the lubricant is introduced into the top third of the vagina, and most preferably at the top of the vagina. The lubricant may be introduced into the vagina

before intercourse, preferably before or during foreplay.

Ideally the lubricant may be introduced into the vagina up to 6 hours before intercourse. However the lubricant is most preferably applied up to an hour prior to sexual activity. This advantageously may allow a woman use the lubricant in privacy, and in particular without her partners knowledge. Alternatively it may be used as part of foreplay together.

Other features of the present invention will become apparent from the following examples. Generally speaking the invention extends to any novel one, or novel combination of the features disclosed in this specification (including any accompanying claims and drawing). Moreover unless stated otherwise, any feature disclosed herein may be replaced by an alternative feature serving the same or a similar purpose.

In order that the invention may be more fully understood, a preferred embodiment of lubricant and delivery device in accordance therewith will now be described by way of example only and with reference to the accompanying illustrative figure which shows a plan view of the dispensing device in accordance with the present invention.

A lubricant was formed by mixing 0.15% w/w of methylparaben, 5% w/w of PEG-40 hydrogenated caster oil and 0.25% w/w of mixed tocopherols 95 in a first vessel. These three ingredients were stirred and warmed slightly. 41.5% w/w of propylene glycol was then added to the first vessel, followed by 5% w/w of aloe vera 10-1 and 18% w/w of a first commercially available lubricant containing water, propylene glycol, glyceryl polymethacrylate, PCM/MA copolymer, methylparaben and propylparaben. In a second vessel 0.1% w/w of Xanthan gum and 15% w/w of water were added and gently stirred to hydrate until the mixture was smooth and uniform. Once fully hydrated the contents of the second vessel were added to the main vessel and mixed until uniform. 15% w/w of a second commercially available lubricant containing water, propylene glycol, glyceryl polymethacrylate, methylparaben and

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- propylparaben was then added to the main vessel and stirred gently until the resulting mixture was smooth and clear. The final lubricant contained 33.87% water, 41.83% propylene glycol and 13.65% of glyceryl polymethacrylate.
- The lubricant is most preferably placed inside a delivery device as shown in the Figure. As can be seen from the Figure the delivery device, which is indicated generally at 1 comprises a squeezable container 2 having an elongate dispensing nozzle 4. The dispensing nozzle 4 is preferably 4.5cm long.

The container 2 and dispensing nozzle 4 are preferably made from a plastics material. The container 2 may be opaque but is most preferably transparent or translucent such that the volume of lubricant 6 held within it can be seen. The dispensing nozzle 4 may be opaque but is preferably also transparent or translucent. Ideally the container 2 also has a volume indicator 8. In a preferred embodiment a tip 10 of the dispensing nozzle 4 has a breakable seal 12.

In use the breakable seal 12 is removed and the dispensing nozzle 4 is inserted into the vagina of a user. The tip 10 of the nozzle 4 is most preferably positioned in the top third of the vagina. Once the tip 10 of the nozzle 4 is in position, the container 2 is squeezed to dispense the lubricant 6 into the vagina.

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5 Claims

- 1. A lubricant comprising from 20 to 50% water, 30 to 50% of an alkylene glycol and 7 to 21% of a glyceryl polmer.
- 10 2. A lubricant according to claim 1 wherein the alkylene glycol is propylene glycol.
 - 3. A lubricant according to claim 1 or 2 wherein the glyceryl polmer is glyceryl polmethacrylate.
 - 4. A lubricant according to any preceding claim further comprising one or more tocopherol and/or tocotrienol compounds.
- 5. A lubricant according to any preceding claim further comprising an aloe compound.
 - 6. A lubricant according to any preceding claim having a viscosity of from 12,000 cps to 17,000 cps.
- 7. A lubricant according to any preceding claim further comprising one or more of methylparaben, propylparaben, potassium sorbate, PEG-40 hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26, trideceth-9, xanthan Gum, methylcellulose,
- $30_{\,\cdot\,}$ hydroxyethylcellulose, hyroxypropylmethylcellulose, . hydroxypropylcellulose, sodium carboxymethylcellulose and/or a PVM/MA copolymer.
- 8. A lubricant comprising one or more tocopherol and/or tocotrienol compounds.
 - 9. A lubricant according to claim 8 further comprising one or more of water, an alkylene glycol and a glyceryl polmer.

- 5 10. A lubricant according to claim 9 wherein the alkylene glycol is propylene glycol.
 - 11. A lubricant according to claim 9 or 10 wherein the glyceryl polmer is glyceryl polmetacrylate.

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- 12. A lubricant according to any of claims 8 to 11 further comprising an aloe compound.
- 13. A lubricant according to any of claims 8 to 12 having a viscosity of from 12,000 cps to 17,000 cps.
 - 14. A lubricant according to any of claims 8 to 13 further comprising one or more of methylparaben, propylparaben, potassium sorbate, PEG-40 hydrogenated castor oil, PEG-40
- 20 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26, trideceth-9, xanthan Gum, methylcellulose, hydroxyethylcellulose, hyroxypropylmethylcellulose, hydroxypropylcellulose, sodium carboxymethylcellulose and/or a PVM/MA copolymer.

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- 15. A lubricant comprising an aloe compound.
- 16. A lubricant according to claim 15 further comprising one or more of water, an alkylene glycol and a glyceryl polmer.

- 17. A lubricant according to claim 16 wherein the alkylene glycol is propylene glycol.
- 18. A lubricant according to claim 16 or 17 wherein glyceryl polmer is glyceryl polmetacrylate.
 - 19. A lubricant according to any of claims 15 to 18 further comprising one or more tocopherol and/or tocotrienol compounds.

- 5 20. A lubricant according to any of claims 15 to 19 having a viscosity of from 12,000 cps to 17,000 cps.
 - 21. A lubricant according to any of claims 15 to 20 further comprising one or more of methylparaben, propylparaben,
- potassium sorbate, PEG-40 hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26, trideceth-9, xanthan Gum, methylcellulose, hydroxyethylcellulose, hyroxypropylmethylcellulose, hydroxypropylcellulose, sodium carboxymethylcellulose and/or a
- 15 PVM/MA copolymer.
 - 22. A lubricant having a viscosity of from 12,000 cps to 17,000 cps.
- 20 23. A lubricant according to claim 22 comprising one or more of water, an alkylene glycol and a glyceryl polmer.
 - 24. A lubricant according to claim 23 wherein the alkylene glycol is propylene glycol.

- 25. A lubricant according to claim 23 or 24 wherein the glyceryl polmer is glyceryl polmethacrylate.
- 26. A lubricant according to any of claims 23 to 25 further comprising one or more tocopherol and/or tocotrienol compounds.
 - 27. A lubricant according to any of claims 23 to 26 further comprising an aloe compound.
- 28. A lubricant according to any of claims 23 to 27 further comprising one or more of methylparaben, propylparaben, potassium sorbate, PEG-40 hydrogenated castor oil, PEG-40 hydrogenated castor oil, polysorbate 20, PPG-26-buthth-26, trideceth-9, xanthan Gum, methylcellulose,
- 40 hydroxyethylcellulose, hyroxypropylmethylcellulose,

- 5 hydroxypropylcellulose, sodium carboxymethylcellulose and/or a PVM/MA copolymer.
 - 29. A delivery device for a lubricant comprising a squeezable container having an elongate dispensing nozzle, wherein the
- 10 dispensing nozzle is from 20mm to 65mm in length.
 - 30. A delivery device for a lubricant according to claim 29 containing a lubricant according to any of claims 1 to 28.
- 15 31. A delivery device for a lubricant according to claim 29 or 30 wherein the container is opaque, transparent or translucent.
 - 32. A delivery device according to any of claims 29 to 31 wherein the container and/or dispensing nozzle further comprises a volume indicator.
 - 33. A delivery device for a lubricant comprising a squeezable container having an elongate dispensing nozzle, wherein the container is opaque, transparent or translucent.

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- 34. A delivery device according to claim 33 wherein the dispensing nozzle is from 20mm to 65mm in length.
- $\,$ 35. A delivery device according to claim 34 containing a $\,$ 30 $\,$ lubricant according to any of claims 1 to 28. $\,$.
 - 36. A delivery device according to any of claims 33 to 35 wherein the container and/or dispensing nozzle further comprises a volume indicator.

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37. A lubricant according to any of claims 1 to 28 for use in the treatment of vaginal dryness.

- 5 38. Use of a lubricant according to any of claims 1 to 28 for the manufacture of a medicament for the treatment of vaginal dryness.
- 39. A method for the treatment of symptoms of vaginal dryness 10 comprising introducing into a vagina a lubricant according to any of claims 1 to 28.
- 41. A method according to claim 40 wherein the lubricant is introduced into the vagina using a delivery device according to any of claims 28 to 36.



 $\bigcup_{i=1}^{n}$

Application No: GB0522423.3 Exa

Examiner: Dr Albert Mthupha

Claims searched: 1-7, 37-39 in part

Date of search: 22 March 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	WO03/043596 A2 (JOHNSON & JOHNSON), see Example 1 (note aqua, glyceryl polymethacrylate, propylene glycol formulation).
A	-	WO03/030793 A1 (CNS INC.), note Example 1.
A	-	WO03/028691 A2 (JOHNSON & JOHNSON), see the Example (note aqua, glyceryl polymethacrylate, propylene glycol formulation).

Categories:

X	Document indicating lack of novelty or inventive	Α	Document indicating technological background and/or state
	step		of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of	P	Document published on or after the declared priority date but before the filing date of this invention.
&	same category. Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X:

Worldwide search of patent documents classified in the following areas of the IPC

The following online and other databases have been used in the preparation of this search report

ONLINE: CAS ONLINE, EPODOC, WPI.