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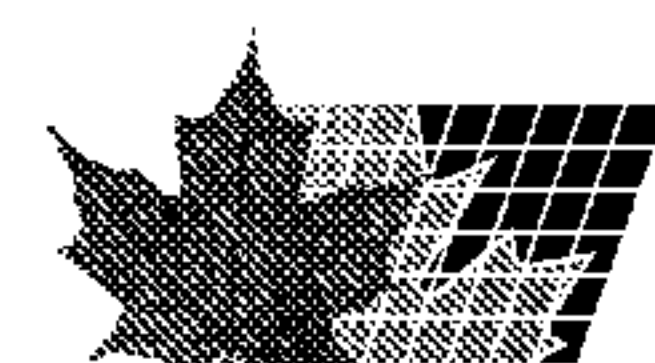
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(54) Titre : DOUCHE VAGINALE AQUEUSE ET METHODES CONNEXES
(54) Title: AQUEOUS VAGINAL DOUCHE AND RELATED METHODS

(57) **Abrégé/Abstract:**

An aqueous vaginal douche which is at most marginally effective against bacteria but which includes a fungicidal/fungistatic agent to rid the vaginal zone of yeasts. The douche may include a penetrating agent and/or an adherent to hold the fungicidal/fungistatic agent to the vaginal tissues. The douche is inserted into the vagina by means of a nozzle or the like. The douche may incorporate a carrier or solvent for the fungicidal/fungistatic agent and may further include a preservative.





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(21) International Application Number: PCT/US91/09722 (22) International Filing Date: 20 December 1991 (20.12.91) (30) Priority data: 633,224 21 December 1990 (21.12.90) US 752,161 21 August 1991 (21.08.91) US (71)(72) Applicant and Inventor: BOMBART, Felice [US/US]; 46 Bacon Road, Old Westbury, NY 11568 (US). (81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent).		Published <i>With international search report.</i>
(54) Title: AQUEOUS VAGINAL DOUCHE AND RELATED METHODS (57) Abstract An aqueous vaginal douche which is at most marginally effective against bacteria but which includes a fungicidal/fungistatic agent to rid the vaginal zone of yeasts. The douche may include a penetrating agent and/or an adherent to hold the fungicidal/fungistatic agent to the vaginal tissues. The douche is inserted into the vagina by means of a nozzle or the like. The douche may incorporate a carrier or solvent for the fungicidal/fungistatic agent and may further include a preservative.		

AQUEOUS VAGINAL DOUCHE AND RELATED METHODSFIELD OF INVENTION

This invention relates to vaginal douches and more particularly to vaginal douches incorporating therein fungicidal/fungistatic (fungicidal and/or fungistatic) agents. This invention also relates to methods for preparing and utilizing vaginal douches which include fungicidal/fungistatic agents.

10

BACKGROUND

There are three types of compositions available for hygienically administering to the vaginal zone. The simplest is essentially water acting as a cleansing agent. A second type contains povidone-iodine. This product is effective against bacteria, but is not effective against fungi. The presence of bacteria in the vagina is desirable, should not be reduced, and does not cause discomfort. The presence of fungal overgrowth in the vagina is undesirable causing discomfort and infection. Therefore, povidone-iodine is herein considered to be unsuitable for preferred hygienic administration to the vaginal zone.

A third type of treatment consists of pharmaceutically acceptable fungicidal/fungistatic compositions which are effective. However, the methods of application for these products are cumbersome and insufficiently effective. The products that are supplied in tablet form require insertion into the vagina with the aid of a mechanical device. The tablet, by itself, must then disintegrate and distribute throughout the vagina to come in contact with the fungi in order to be effective. This method of treatment is not very effective. Miconazole nitrate supplied in a cream formulation is also cumbersome to apply vaginally and the difficulty of thorough distribution to all tissue surfaces reduces its effectiveness.

In reviewing prior art patents, relative to the preparation of this application there were uncovered U.S. patents, 3,011,946 (Bartner et al.); 4,195,172 (Falkowski et al.); and 4,102,998 (Gutnick).

The Bartner patent reveals an aqueous solution of nystatin developed to be highly soluble in an aqueous solution of a soluble saccharin. The discovery is disclosed that the incorporation of benzyl alcohol into the solution
5 imparts an improved solubility to the nystatin. According to the patentee, nystatin preparations are parenterally administered and administration is intended to be by injection in an intramuscular or intravenous fashion. This is different from the administration of a vaginal douche by
10 means of a nozzle or the like.

The Falkowski patent relates to salts of various compounds including nystatin which are of very high water solubility. The resulting compounds are said to exhibit antifungal activity especially against yeast-like fungi.
15 This patent relates to injectable solutions and not to the administration of douches. One of the specified nystatin salts derived is N-methylglucamine salt of the N-glycosyl derivative of nystatin.

The Gutnick patent relates to a process for the
20 prevention of venereal disease. It discloses an embodiment in which a metal intrauterine contraceptive device is provided for medication which is released gradually into the vagina and the lower end of the uterus over a prolonged period of time. This patent relates to antibacterials and
25 antibiotics and the device includes a magnet. Reference is also made to antifungal activity in other places in the text of this patent, but nystatin is referred to as an antibiotic with antifungal activity. No reference is made to a water soluble nystatin.

30 None of the known prior art nor the foregoing patents relates to the preparation of a fluid douched especially suited for killing or inhibiting fungi such as yeast in the vaginal zone while being at most marginally effective with respect to bacteria.

35 SUMMARY OF INVENTION

It is an object of the invention to provide an improved vaginal douche.

It is another object of the invention to provide an improved vaginal douche capable of eradicating or minimizing the presence of fungi.

5 It is still another object of the invention to provide an improved aqueous vaginal douche capable of eradicating fungi while being a most marginally effective relative to bacteria of the type normally found in the vaginal zone.

10 It is still another object of the invention to provide an improved vaginal douche and methods for the use thereof based on the recognition of the fact that it is harmful to remove the bacteria from vaginal zones and on the basis of the recognition that it is of substantial importance to eradicate fungi such as yeast in the vaginal
15 zone.

In achieving the above and other objects of the invention, there is provided a method comprising effecting hygienic care of a vaginal zone by introducing into the vaginal zone a fluid douche into which has been incorporated
20 a fungicidal/fungistatic agent. More particularly, the fungicidal/fungistatic agent which is employed in accordance with the invention has at most a marginal effectiveness against bacteria especially of the type normally found in the vaginal zone.

25 As features of the invention, the method thereof further comprises enhancing the penetration of the douche into the vaginal zone by incorporating into the douche a penetrating agent. According to a further feature of the invention there is comprised in the method thereof the
30 enhancing of adhering of the fungicidal/fungistatic agent to the tissue in the vaginal zone by incorporating into the douche an adherent adapted to retain the fungicidal/fungistatic agent in the vaginal zone.

Preferably in accordance with the invention the
35 fluid douche is prepared with water as the fluid whereby to form an aqueous douche. Preferably the adherent is a gum such as for example selected from the group consisting of arabic, algin, guar, tragacanth, pectin, dextran and xanthan. The aforesaid gums are natural gums. A further

group which is useful in providing an adherent in accordance with the invention is a modified natural gum. These may be selected from the group consisting of sodium carboxymethyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxyethyl methyl cellulose. The gum employed in accordance with the invention may also be a synthetic gum such as polyvinyl alcohol and acrylic acid. Acidic gums may be used as is or as their salts, for example, formulated with sodium or potassium hydroxide, or organic amines such as triethanol amine, monoisopropanol amine or di-(2-ethyl hexyl) amine.

The penetrant which is employed may be a nonionic agent selected from the group consisting of ethoxylated alcohols, ethoxylated alkyl phenols, ethoxylated fatty acids, ethoxylated castor oil, alkanolamides, ethylene glycol/propylene glycol copolymers, ethoxylated sorbitol, ethoxylated sorbitol esters and ethoxylated glycerol esters. The penetrant may be an anionic agent selected from the group consisting of alkyl sulfosuccinates, alkyl sulfonates and sulfates, alkyl aryl sulfonates and sulfates, phosphate esters and betaines.

In accordance with the invention the fungicidal/fungistatic agent may be of various types. Some examples which are employed in accordance with the invention include miconazole, 1-[2-(2,4-dichlorophenyl)-2-[2,4-dichlorophenyl) methoxy]ethyl]-1H-imidazole; clotrimazole, 1-[(2-chlorophenyl) diphenylmethyl]-1H-imidazole; ketoconazole, cis-1-acetyl-[4-(4-[[2-(2,4-dichlorophenyl)-2-(1H-imidazole-1-ylmethyl)-1,3-dioxolan-4-yl]-methoxy]phenyl]piperazine; and nystatin.

According to the invention the dispersion and solution of the fungicidal/fungistatic agent in water may be enhanced by incorporating a carrier or solvent into the douche. The carrier may be for example polyethylene glycol or polypropylene glycol and preferably one having a molecular weight range from about 200-2000.

Preferably the douche will be adjusted to a pH of about 5.5-8.5. In addition there may be incorporated a preservative in the douche such as for example methylparaben

or propylparaben. The douche of the invention is introduced into the vaginal zone via a nozzle inserted therein.

This invention also relates to the provision of a product. This product comprises a vaginal douche including
5 a fungicidal/fungistatic agent having at most a marginal effectiveness against bacteria. The vaginal douche is in accordance with the invention an aqueous douche. Preferably the aqueous douche includes a penetrating agent and/or an adherent of the above noted type.

10 The above and other objects, features and advantages will become apparent from the following detailed description of some preferred embodiments thereof.

DETAILED DESCRIPTION

The purpose of this product is to provide prompt
15 hygienic direct relief from vaginal itch and irritation caused by fungal overgrowth and fungal types of infection. This preparation is in the form of a douche for easily administered direct (refreshing) application.

Vaginal itch and irritation secondary to fungal
20 overgrowth is a very common problem plaguing approximately 50% of the female population. This type of vaginitis is caused by fungal overgrowth.

A mild amount of fungal overgrowth will cause persistent itch, irritation and foul smelling discharge. A
25 substantial amount of fungal overgrowth causes unbearable constant itching, severe inflammation and profuse foul smelling discharge, and therefore an enormous amount of discomfort. Fungal infections are communicable.

In normal amounts, vaginal bacteria keeps in check
30 or limits fungal overgrowth. Therefore, any alteration of the proportion between fungal and bacterial flora in the vagina directly stimulates fungal overgrowth. A decrease in the amount of normal vaginal bacterial flora will allow fungal overgrowth.

35 Altered and/or decreased vaginal bacterial flora is caused by 1) antibiotic therapy, 2) chemotherapy, 3) altered immunologic conditions such as AIDS, De George Syndrome and cancer, 4) stress and 5) poor nutrition.

Fungal overgrowth is also caused by altered metabolic states such as diabetes mellitus.

For those females with the condition of diabetes mellitus, fungal overgrowth in the vagina is a chronic
5 problem and requires constant treatment throughout ones lifetime. A significant amount of so-called healthy females also have chronic yeast overgrowth of unknown etiology.

Presently on the market there is no douche or over-the-counter product of any form that can treat fungal
10 overgrowth in the vagina. On the contrary, any aqueous product or douche used in the vagina will cause alterations in the normal balance between bacteria and fungi and/or decrease bacterial flora, thereby promoting fungal overgrowth.

15 There is also on the market a douche containing a povidone-iodine solution which is bactericidal, therefore decreasing the amount of bacteria and directly promoting fungal overgrowth.

In prescription form there exists treatments with
20 pharmaceutically acceptable fungicidal/fungistatic compositions which are effective. However, the method of application for these products is cumbersome and insufficiently effective. The products are supplied in tablet and cream form and require insertion into the vagina
25 with the aid of a mechanical device. The tablet by itself must then disintegrate and distribute throughout the vagina to come in contact with the fungi in order to be effective. This method of treatment is not very effective. Miconazole nitrate supplied in a cream formulation is also cumbersome
30 to apply vaginally using a mechanical device and the difficulty of thorough distribution to all tissue surfaces reduces its effectiveness.

The invention overcomes the above deficiencies by providing an effective product in a form that is easy to
35 use. The product is formulated such that it can be rapidly distributed throughout the vagina or vaginal zone for purposes of reaching all tissue surfaces. Ingredients may, in accordance with the invention, be included in the

composition to enhance penetration and adherence to the tissue surfaces in the vaginal zone.

Pharmaceutically acceptable fungicidal/fungistatic agents for the product include miconazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl) methoxy]ethyl]-1H-imidazole; clotrimazole, 1-[(2-chlorophenyl) diphenylmethyl]-1H-imidazole; ketoconazole, cis-1-acetyl-4-[4[[2-(2,4-dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]-methoxy]phenyl]piperazine; and nystatin.

These substances are known for their fungicidal/fungistatic properties. The first three are synthetic substances; the last, nystatin, is polyene antibiotic obtained from a microorganism culture. Their effectiveness against bacteria is marginal and, therefore, they will not disturb the bacterial balance in the vagina.

The composition of the invention may be modified by incorporating a gum to provide adherence to the vaginal tissues. Natural gums may be used such as arabic, algin, guar, tragacanth, pectin, dextran, and xanthan. Modified natural (semisynthetic) gums may be used such as sodium carboxymethyl cellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and hydroxyethyl methyl cellulose. Synthetic gums such as polyvinyl alcohol and acrylic acid may also be used. Acidic gums may be used as is or as their salts, for example, formulated with sodium or potassium hydroxide, or organic amines such as triethanol amine, monoisopropanol amine or di-(2-ethyl hexyl) amine.

A penetrant is incorporated to hasten and improve the penetration and adherence of the fungicide to the tissue surfaces. Nonionic penetrants may be used such as ethoxylated alcohols, ethoxylated alkyl phenols, ethoxylated fatty acids, ethoxylated castor oil, alkanolamides, ethylene glycol/propylene glycol copolymers, ethoxylated sorbitol, ethoxylated sorbitol esters and ethoxylated glycerol esters.

Anionic penetrants may also be used such as alkyl sulfosuccinates, alkyl sulfonates and sulfates, alkyl aryl sulfonates and sulfates, phosphate esters and betaines.

The compositions also contain a carrier or solvent for the components to assist in the dispersion and solution

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of the ingredients in water for efficient introduction and distribution within the vaginal. No mechanical device is required as with the use of a fungicide in tablet form although a nozzle is used for hydraulic purposes. Suitable carriers are polyethylene glycols (PEG), also known as polyoxyethylene glycols (POE), and polypropylene glycols (PPG), also known as polyoxypropylene glycols (POP). Grades in the molecular weight range 200-2000 are suitable. A 400 molecular weight grade is preferred.

Minor percentages (for example, up to about 1%) of other components may be included in the following examples to render the compositions more pharmaceutically desirable. The pH may be adjusted to 5.5-8.5 as desired with lactic acid, citric acid, their sodium salts, or similar substances. Preservatives may be added as desired, such as methylparaben, propylparaben or similar substances. Suitable fragrances may be added as desired.

EXAMPLE 1

20	Miconazole	Wt%
	Tragacanth	1-3
	*Nonyl phenol polyethylene glycol	1-3
	Polyethylene glycol 400	1-3
		<u>97-99</u>
25	* Tergitol™/NP-10 (Union Carbide Corp)	100
	containing 10.5 mols of ethylene oxide.	

All ingredients are mixed at 20-50 degrees Celsius producing a solution or dispersion in the glycol. 4-5 parts of the product are mixed with 100-10 parts of water producing a concentration of 0.025-0.1% clotrimazole for vaginal treatment. Insertion into the vaginal zone is by means of a nozzle or the like.

The following Examples 2-6 are prepared in the same manner as that used for Example 1.

EXAMPLE 2

40	Clotrimazole	Wt%
	*Polyacrylic acid	1-3
	Triethanol amine	1-3
	**Ethoxylated castor oil	1-3
	Polyethylene glycol 400	1-3
		<u>96-98</u>
		100

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* Carbopol™ 934; Goodrich Chemical Co. **POE
 (4) Castor oil; Trylox™ CO-40, Code 5909; Henkel Corp.,
 Emery Group

5

EXAMPLE 3

	Ketoconazole	<u>Wt%</u>
	Pectin	1-3
10	Nonyl phenol polyethylene glycol	1-3
	Polyethylene glycol 400	1-3
		<u>97-91</u>
		100

15

EXAMPLE 4

	Nystatin	<u>Wt%</u>
	Dextran	1-3
	Ethoxylated castor oil	1-3
20	Polyethylene glycol 400	10-30
		<u>88-64</u>
		100

EXAMPLE 5

25	Clotrimazole	<u>Wt%</u>
	Ethoxylated castor oil	1-3
	Polyethylene glycol 400	10-30
		<u>89-67</u>
30		100

EXAMPLE 6

35	Clotrimazole	<u>Wt%</u>
	Polyacrylic acid	1-3
	Triethanol amine	1-3
	Polyethylene glycol 400	1-3
		<u>97-91</u>
		100

40

***EXAMPLE 7

	(A) Clotrimazole	<u>Wt%</u>
	Polyethylene glycol 400	1-3
45		<u>99-97</u>
		100
	(B) Algin	1-5
	Nonyl phenol polyethylene glycol	.01-.5
50	Water	<u>98.99-94.5</u>
		100

*** (A) is prepared by mixing the ingredients at 20-30
 degrees Celsius 4-5 parts of (A) are added and mixed with
 100-150 parts of (B) at ambient temperature and used
 immediately as a vaginal douche.

55

***EXAMPLE 8

5	(A)	Clotrimazole	<u>Wt%</u> 1-3
		Ethoxylated castor oil	<u>99-97</u> 100
10	(B)	Arabic	1-5
		Water	<u>99-95</u> 100

##EXAMPLE 9

15	Clotrimazole	<u>Wt%</u> .03-.2
	Polyacrylic acid	.03-.2
	Triethanol amine	.03-.2
	Ethoxylated castor oil	3-20
	Water	<u>96.91-79.4</u> 100
20		

All ingredients are mixed at 20-50 degrees Celsius.

##EXAMPLE 10

25	(A)	Clotrimazole	<u>Wt%</u> 1-3
		Ethoxylated castor oil	<u>99-97</u> 100
30	(B)	Polyacrylic acid	.03-.2
		Triethanol amine	.03-.2
		Water	<u>99.94-99.6</u>
			100
35			

There will now be obvious to those skilled in the art many modifications and variations of the method and products set forth hereinabove. These modifications and variations will not depart from the scope of the invention if defined by the following claims.

SUBSTITUTE CLAIMS

1. An aqueous vaginal douche composition comprising an effective amount of an antifungal agent having fungicidal/fungistatic properties and essentially minimal antibacterial activity, a penetrating agent and an adherent agent, wherein said douche composition has a low viscosity and is essentially free of zinc-containing compounds.

2. The douche composition of claim 1 wherein the antifungal agent is selected from the group consisting of miconazole, clotrimazole, ketoconazole, nystatin, 1-[2-(2,4-dichlorophenyl)-2-[2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole, 1-[(2-chlorophenyl)diphenylmethyl]-1H-imidazole, and cis-1-acetyl-4-(4[[2-(2,4-dichlorophenyl)-2 (1H-imidazole-1-yl)methyl)-1,3-dioxolan-4-yl]-methoxy]phenyl] piperazine.

3. The douche composition of claim 1 wherein the antifungal agent is selected from the group consisting of miconazole, clotrimazole, ketoconazole and nystatin.

4. The douche composition of claim 1 wherein the effective amount of antifungal agent is between 0.03-3.0 weight percent of the composition.

5. The douche composition of claim 1 wherein the penetrating agent is selected from the group consisting of nonionic and anionic agents.

6. The douche composition of claim 5 wherein the penetrating agent is a nonionic agent selected from the group consisting of ethoxylated alcohols, ethoxylated allyl phenols, ethoxylated fatty acids, ethoxylated castor oil, alkanolamides, ethylene glycol/propylene glycol copolymers, ethoxylated sorbitol, ethoxylated sorbitol esters and ethoxylated glycerol esters.

7. The douche composition of claim 5 wherein the penetrating agent is an anionic agent selected from the group consisting of alkyl sulfo succinates, alkyl sulfonates, alkyl sulfates, alkyl aryl sulfonates, alkyl aryl sulfates, phosphate esters and betaines.

8. The douche composition of claim 1 wherein the adherent agent is selected from the group consisting of natural gums, modified natural gums, acidic gums and synthetic gums.

9. The douche composition of claim 8 wherein the natural gum is selected from the group consisting of arabic, algin, guar, tragacanth, pectin, dextran and xanthan gums.

10. The douche composition of claim 8 wherein the modified natural gum is selected from the group consisting of sodium carboxymethylcellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxyethyl methyl cellulose.

11. The douche composition of claim 8 wherein the synthetic gum is selected from the group consisting of polyvinyl alcohol and polyacrylic acid.

12. The douche composition of claim 1 further comprising a carrier or solvent.

13. The douche composition of claim 12 wherein the carrier is selected from the group consisting of polyethylene glycols, polyoxyethylene glycols, polypropylene glycols and polyoxypropylene glycols.

14. The douche composition of claim 13 wherein the carrier has a molecular weight between 200-2000.

15. The douche composition of claim 14 wherein the carrier has a molecular weight of 400.

16. The douche composition of claim 1 further comprising a preservative.

17. The douche composition of claim 16 wherein the preservative is selected from the group consisting of methylparaban and propylparaban.

18. The douche composition of claim 1 having a pH of about 5.5 to 8.5.

19. Use of an aqueous vaginal douche composition comprising an effective amount of an antifungal agent having fungicidal/fungistatic properties and essentially minimal antibacterial activity, a penetrating agent and an adherent

agent, wherein said douche composition has a low viscosity and is essentially free of zinc-containing compounds, for the prevention or treatment of a yeast or fungal infection.

20. The use according to claim 19 wherein the antifungal agent is selected from the group consisting of miconazole, clotrimazole, ketoconazole, nystatin, 1-[2-(2,4-dichlorophenyl)-2-[2,4-dichlorophenyl)methoxy]ethyl]-1H-imidazole, 1-[(2-chlorophenyl)diphenylmethyl]-1H-imidazole, and cis-1-acetyl-4-4[[2-(2,4-dichlorophenyl)-2(1H-imidazole-1-ylmethyl)-1,3-dioxolan-4-yl)-methoxy]phenyl]piperazine.

21. The use of claim 19 wherein the antifungal agent is selected from the group consisting of miconazole, clotrimazole, ketoconazole and nystatin.

22. The use of claim 19 wherein the effective amount of antifungal agent is between 0.03-3.0 weight percent of the composition.

23. The use of claim 19 wherein the penetrating agent is selected from the group consisting of nonionic and anionic agents.

24. The use of claim 23 wherein the penetrating agent is a nonionic agent selected from the group consisting of ethoxylated alcohols, ethoxylated allyl phenols, ethoxylated fatty acids, ethoxylated castor oil, alkanolamides, ethylene glycol/propylene glycol copolymers, ethoxylated sorbitol, ethoxylated sorbitol esters and ethoxylated glycerol esters.

25. The use of claim 23 wherein the penetrating agent is an anionic agent selected from the group consisting of alkyl sulfo succinates, alkyl sulfonates, alkyl sulfates, alkyl aryl sulfonates, alkyl aryl sulfates, phosphate esters and betaines.

26. The use of claim 19 wherein the adherent agent is selected from the group consisting of natural gums, modified natural gums, acidic gums and synthetic gums.

27. The use of claim 26 wherein the natural gum is selected from the group consisting of arabic, algin, guar, tragacanth, pectin, dextran and xanthan gums.

28. The use of claim 26 wherein the modified natural gum is selected from the group consisting of sodium carboxymethylcellulose, methyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxyethyl methyl cellulose.

29. The use of claim 26 wherein the synthetic gum is selected from the group consisting of polyvinyl alcohol and polyacrylic acid.

30. The use of claim 19 wherein the douche composition further comprises a carrier or solvent.

31. The use of claim 30 wherein the carrier is selected from the group consisting of polyethylene glycols, polyoxyethylene glycols, polypropylene glycols and polyoxypropylene glycols.

32. The use of claim 30 wherein the carrier has a molecular weight between 200-2000.

33. The use of claim 30 wherein the carrier has a molecular weight of 400.

34. The use of claim 19 wherein the douche composition further comprises a preservative.

35. The use of claim 34 wherein the carrier has a molecular weight of 400.

36. The use of claim 19 wherein the douche composition has a pH of about 5.5 to 8.5.

37. The use of claim 19 wherein the aqueous douche composition is introduced into the vagina by means of a nozzle inserted into the vagina.

38. The use of claim 37 wherein the nozzle is attached to a reservoir containing the aqueous douche composition.