

1

3,091,241

VAGINAL TAMPON

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This invention relates to improvements in catamenial devices such as vaginal tampons and sanitary napkins.

An important object of the invention is to provide improvements in catamenial devices of the type used primarily for normal menstrual use as well as the type used primarily for therapeutic treatment of the female genitalia, and particularly the vaginal tract.

Another object is to provide a medicated catamenial tampon which effectively maintains or restores the normal ecological balance of the vagina, prevents putrefactive activities of microbial growth, is non-irritating and non-toxic, and which may safely be used without a medical prescription.

A further object is to provide a catamenial tampon which acts as a physiological biostat or automatic controller for any microorganic imbalance which may exist in the immediate area of use.

Another object is to provide an improved medicated catamenial device which remains highly effective as a deodorant during a normal use period.

Other objects and advantages will become apparent to persons skilled in the art, as will various modifications thereof without departure from the inventive concepts defined in the appended claims.

There exists in the female body a complicated process which maintains the vagina and other related delicate areas in a normal healthy state most of the time. During the menses, however, this normal healthy state of the vaginal area is disrupted to some extent and at such time the vagina may become more susceptible to infection than usual. Such infection is commonly called vaginitis, a condition which develops more easily in some women than others, and which is frequently associated with their monthly discharge period. The danger of infection increases during this time because foreign microorganisms or other outside sources of infection may be introduced through careless handling of sanitary napkins, or more especially, through careless handling and insertion of absorbent tampons. The concept herein taught minimizes the possibility of such infection occurring.

The normal vaginal environment in the adult female results from a complicated harmony of hormonal, cytologic, and bacterial factors which develop at puberty, when glycogen is deposited in the vaginal wall and the secretion becomes acid. The normal flora of the vagina seems to depend largely on the glycogen content of the vaginal epithelium, which later is further dependent on ovarian activity. The flora of the vagina is mixed, consisting of varied staphylococci, streptococci, coliform and diphtheroid bacilli, a few yeasts and fungi but predominantly of *Bacillus vaginalis* or Döderlein's bacillus. The normal vaginal secretion has a marked bactericidal action, largely ascribed to the presence of lactic acid, although other factors probably are concerned. The lactic acid itself is derived from the glycogen, partly as a result of natural enzymes, but mainly due to the fermentative activity of Döderlein's bacillus.

Vaginitis is often the result of an unbalancing of these factors and frequently is evidence of altered microflora or physiology in the vagina. When the normal condition is altered, the pH generally increases and an inflammatory condition can result, often caused by the predominance of a yeast-like growth, *Candida albicans* (moniliasis), and sometimes by a protozoa, *Trichomonas vaginalis*.

2

Indications are that these diseases have become more prevalent in recent years, probably as the result of increased antibiotic therapy which often upsets the normal bacterial balance.

Under normal conditions, estrogen secretion stimulates the growth of glycogen bearing epithelial cells. These cells metabolize and degenerate, releasing lactic acid. This acid creates a favorable environment for normal vaginal flora, including the lactobacillus, which perpetuates the cycle in turn by reacting on the glycogen bearing cells. The resulting pH is from 3.8 to 4.5 which is generally considered the most favorable condition for maintenance of normal flora. At that pH, the vagina normally harbors numerous species of microorganisms which, when present in a balanced ecology, play a beneficial role in providing protection and resistance to infection.

During menstruation, a slightly alkaline pH is frequently established with attendant sloughing of epithelial tissue. Thus, less lactic acid is released and the pH tends to remain alkaline. Such conditions favor the onset of vaginitis, since in an alkaline environment an overgrowth of putrefactive microorganisms may develop followed by inflammation.

The present invention provides an efficient means for therapeutic treatment of the vaginal tract at the time in the monthly cycle when such treatment is most beneficial. It serves to reduce to a minimum the possibility of contracting vaginitis during menses and serves further to relieve such conditions, if already developed, by providing a specially treated absorbent tampon which acts as a physiological biostat, i.e. automatically maintains and controls the normal ecological balance of the vagina.

According to this invention, there is provided to perform this unusual biostatic function, an absorbent tampon containing controlled amounts of glyceryl triacetate (triacetin).

The biostatic effect of triacetin, as observed by Dr. S. G. Knight of the University of Wisconsin is reported in Johnson et al., A.M.A. Arch. Dermatology, vol. 74, pages 73-75 (1956); Knight, Antibiotics and Chemotherapy, vol. VII, pages 172-4 (1957); Knight, J. Investigative Dermatology, vol. 28, pages 363-6 (1957); and Burack et al., J. Investigative Dermatology, vol. 30, pages 197-9 (1958).

Glyceryl triacetate, or triacetin, is readily broken down into glycerol and acetic acid by the enzymatic action of esterase. Esterase is abundantly present in the vaginal epithelium and serum released during menses. The enzymatic action of the esterase is in turn controlled by the pH of the environment, and is more active when the pH is on the alkaline side. Since the pH of the vaginal area moves toward the alkaline side during menstruation, i.e. to a pH of about 6 to 8, the enzymatic activity of esterase automatically increases and attacks the triacetin carried by the tampon, which releases acetic acid rapidly. As the acid is released, the pH drops to a level of about 4 causing a decrease in esterase activity which, in turn, slows the breakdown of triacetin and coincident release of acid. As the normal menstrual function goes on, its tendency toward an alkaline environment continues to neutralize any acids present causing the pH to rise again and reinitiate esterase activity. This, in turn, releases more acetic acid to again lower the pH. The decreasing pH also automatically keeps the acetic acid in physiologic bounds by inhibiting the rate of esterase activity and subsequent release of more acid. This constant low concentration of acetic acid acts as a continuing mild biostatic agent which prevents multiplication of harmful microorganisms without detrimental effect on the normal vaginal flora. The triacetin is thus not limited to a

single active cycle, but maintains its therapeutic effect until exhausted.

This interrelated cooperation of the enzymatic action of the esterase and the decomposition of the triacetin, therefore, acts favorably in restoring the pH of the vagina to its normal healthy range and maintaining it there. It has been found that the concentration of acetic acid so produced is not irritating or harmful to the tissues, even over extended time periods. The mild biostatic action is not spermicidal, nor does it attack the useful microorganisms usually present. The interaction which takes place is comparable to the use of a constant vinegar douche. This action of maintaining the pH of the vagina within its normal acid range is most important in preserving its ecological balance.

The fungicidal and bactericidal values of the fatty acids, including acetic acid, have been known for many years. However, they have not found wide use because they are irritating and corrosive at high concentration, and lose their effectiveness comparatively fast either because they may volatilize too fast, or diffuse away from the site of an infection being treated, or become neutralized to their relatively ineffective salts. The discovery of the unique action of triacetin has made it possible to utilize it as a self-regulating agent, mild enough to be biostatic rather than biocidal, which does not have the above-listed disadvantages. The self-regulating action assures the maintenance of a therapeutic level of free fatty acid at the site of infection or potential infection, and at the same time prevents irritation which might be caused by overtreatment such as too high a concentration of acid.

Many types of treatment for vaginitis have been tested and used in the past, but none has been universally satisfactory. Local treatment of infected areas has included the use of sulfa cream; arsenics or picric acid derivatives; lactose tablets; silver nitrate; gentian violet; antibiotics; mild acid douches and others. Antibiotics such as aureomycin, chloramphenicol, penicillin, dihydrostreptomycin and terramycin have been used both orally and parenterally with some local and favorable effect on abnormal vaginal flora, but, as noted before, this often upsets the ecological balance and may cause side effects because of sensitivity and the like.

The use of non-absorbent vaginal inserts such as suppositories or medicated lamb's wool is not practical during the menstrual period, although they have been used at such time, but only with difficulty. Now, the combination of an absorbent tampon with a new therapeutic agent for vaginitis provides a convenient method for the local treatment of infection during menstruation as well as at other times.

Thus it can be seen that an absorbent tampon containing triacetin is far superior to ordinary tampons. If it is used under conditions of normal pH, it will absorb body fluids efficiently as ordinary tampons do. However, if conditions foster an alkaline pH the tampon will provide therapeutic action by releasing acetic acid in close proximity to the source of infection. The acetic acid acts as a bacteriostat and at the same time tends to return the tissue to a normal pH of between about 3.8 to 4.5 and encourage re-establishment of the normal bacterial flora which aid in resisting further infection. The coincident release of glycerol is also beneficial to the vaginal area because of its well known emollient effect on the skin or mucous membrane.

An additional advantage is that triacetin functions as a deodorant by inhibiting the overgrowth of putrefactive microorganisms, thus stopping odors by destroying their source rather than merely masking odors which already exist.

The triacetin also acts as a softening agent on fibers, fabrics, and sponges treated therewith, giving them a smoother, softer finish. This is an especially desirable property for catamenial devices generally. It provides easier insertion for tampons thus treated, and gives more

comfort while they are in place. When wrappers for sanitary napkins are thus treated, protection against chafing results together with better all around comfort when worn.

Triacetin has been tested against a mixed culture of microorganisms isolated from menstrual exudates. All tests were carried out in a blood or serum based agar which contained the required enzyme necessary for the release of the acetic acid from triacetin. These conditions closely simulated natural conditions of use.

Concentrations of 1 percent triacetin per 99 percent of the agar provided:

- (1) Mild bacteriostatic properties, i.e. the arresting of bacterial growth,
- (2) Some selective action against certain microorganisms particularly yeasts and fungi frequently associated with vaginitis,
- (3) A safe "threshold odor value" (the minimum concentration of test material required to inhibit odor under standard test conditions).

Other tests, in which tampons were treated with triacetin in controlled amounts, indicated concentrations of triacetin starting as low as 0.25 percent by weight, based on weight of the absorbent material being treated, had beneficial effects. Excellent results were obtained with concentrations of between 1 percent and 2.5 percent triacetin by weight. However, the invention is not so limited, and under certain conditions, such as in tampons specifically designed for therapeutic use, concentrations up to 5 percent and higher may be employed. No bactericidal action (killing of microorganisms) results from employment of concentrations up to 5 percent. Further, when used in such concentration with tampons, there was no spermicidal action.

If the concentrations of triacetin are present in excess of 5 percent by weight, the tampon often takes on an oily appearance which might be objectionable for ordinary menstrual use, but is readily acceptable when used for medication purposes.

Vaginal tampons suitable for use in this invention are usually made of absorbent fibers, including natural and synthetic fibers, compressed into a unitary body of a size which may easily be inserted into the vaginal cavity. They are normally made in an elongated cylindrical form in order that they may have a sufficiently large body of material to provide the required absorbing capacity, but may be made in a variety of shapes. The tampon may or may not be compressed, although compressed types are now generally preferred. The tampon described in U.S. Patent 2,761,449, dated September 4, 1956, is typical. This patent shows a tampon made of various fiber blends including both absorbent and nonabsorbent fibers, which may or may not have a suitable jacket or wrapper. Tampons of this type may be treated with triacetin in various ways. For example, the wrapper only may be impregnated; the absorbent fibers only may be impregnated; or the entire tampon assembly may be dipped.

Newer style tampons made from absorbent micro-porous sponge material such as described in U.S. Patent 2,880,726, dated April 7, 1959, may also be treated in the manner herein described.

Any conventional method may be used for applying the triacetin to the absorbent elements. One method is by passing the material to be impregnated through a liquid bath of pure triacetin. Dilution with solvents and the like is ordinarily not necessary when high concentrations are desired, since triacetin is a clear liquid slightly more viscous than water. However, to more easily control the amount picked up by the material being treated, solvents, such as ethyl alcohol or ether or their aqueous solutions, may be used to dilute the impregnating bath.

Unitary tampons without separate wrappers may be dipped directly into the bath and air dried, when neces-

sary to remove any volatile solvents. For compressed tampons, impregnating of any of its elements is best done before compressing.

If the tampon is provided with a separate permeable wrapper, the wrapper alone may be impregnated by passing it through a triacetin bath on conventional textile padding equipment, or the like, before the tampon is wrapped and compressed. Conventional drying methods for fabrics may also be used when necessary. Obviously the complete assembly could also be dipped as with unitary tampons.

It is not necessary to impregnate the entire absorbent body of the tampon with the triacetin. Optimum results both economically and functionally, are obtained by concentrating the material on or near the outer surface where it will be most effective during use. Some migration of the triacetin takes place in the treated pad, as is true of all glycerol-like substances over a period equivalent to normal shelf life, but the highest concentrations will remain in the general area where it has been applied originally.

Another method found useful for applying the triacetin is to treat the loose absorbent fibers before they are formed into an absorbent pad by soaking them in the triacetin, subsequently drying the fibers where necessary, and forming the treated fibers, alone or in combination with untreated fibers, into pads of desired size and shape. The loose fibers could also be treated by spraying with triacetin in the forming chamber when air-forming methods are used to form pads.

It is also contemplated to use the triacetin in combination with externally worn sanitary napkins. When the wrapper or external elements of such napkins are treated as taught herein, the napkins have a softer cosmetic feel and may be worn with more comfort. In addition there is provided the deodorizing action previously described, along with some therapeutic value which develops wherever the napkin is in contact with the external genitalia. This is useful in cases where the latter

are easily irritated or subject to minor infections. When the internal elements of sanitary napkins only are treated with triacetin, the deodorizing properties predominate.

What is claimed is:

5 1. A compressed vaginal tampon adapted for easy insertion and expansion within the vaginal cavity under normal conditions of use and for absorbing and retaining catamenial fluid while maintaining a normal ecological balance in the cavity during menses, said tampon comprising, as the fluid absorbing and retaining means, a compressed absorbent body, and as means for maintaining said normal ecological balance, glyceryl triacetate, said glyceryl triacetate being present at least in the outer peripheral area of said body in the amount of from 10 about 0.25 percent to 5.0 percent by weight based on the total weight of said body, said tampon being non-toxic, non-irritating, and non-spermicidal in use.

15 2. A compressed vaginal tampon adapted for easy insertion and expansion within the vaginal cavity under normal conditions of use and for absorbing and retaining catamenial fluid while maintaining a normal ecological balance in the cavity during menses, said tampon comprising, as the fluid absorbing and retaining means, a compressed absorbent body comprised of absorbent fibers 20 and an outer wrapper of absorbent fluid pervious material, and as the means for maintaining said normal ecological balance, glyceryl triacetate, said glyceryl triacetate being present at least in the outer peripheral area of said body in the amount of from about 0.25 percent to 5.0 percent 25 by weight based on the total weight of said body, said tampon being non-toxic, non-irritating, and non-spermicidal in use.

FOREIGN PATENTS

35 727,631 Great Britain Apr. 6, 1955

OTHER REFERENCES

Knight: Investigative Dermatology Journal, volume 28, pages 363-6, 1957. (Copy in Scientific Library.)