

DUREX • NOTES

Issued by DUREX PRODUCTS, INC., 156 Fifth Avenue, New York, N. Y.

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To AFFORD physicians a more complete service, DUREX LABORATORIES have experimented with and developed through its regular channels*, five new vaginal jellies, in addition to its Lactikol formulae.

The reasons for offering several formulae are ample. As a result of the increased interest in the science of contraception on the part of physicians and clinics no one type of vaginal jelly will answer all requirements.

Not only have we developed jellies designed both to constitute a mechanical barrier and to immobilize spermatozoa but also have varied them sufficiently in composition so that at least one would be suitable for any type of patient, regardless of personal idiosyncrasy. Reports to us from clinics and from private physicians using and prescribing jellies have indicated that:

1. A small proportion of patients have an idiosyncrasy to quinoline** compounds.
2. A small proportion of patients are very sensitive to high acidity (low pH value) in a jelly. It may cause burning or other discomfort at the concentration best for spermicidal action.

All Durex jellies are carefully compounded to give a suitable viscosity so that some mechanical barrier action to the passage of sperm is obtained as well as sufficiently low surface tension to penetrate the minute crevices in the vaginal walls. This viscosity is sufficient to practically eliminate any dripping and its attendant discomforts. The jelly base in every case except one is Durekol. In the case of one jelly — Lactikol A, a starch-glycerin base is used.

The Durekol base is easily miscible with the spermatic and vaginal fluids — which is essential for its success in actual use. It is prepared from

natural carbohydrate gums by a special process. Its effectiveness is due, not only to its physical properties, but to the fact that this base is somewhat spermicidal in itself without the addition of any acid.

We have tested the base itself as well as the various jellies made from it, on active human spermatozoa by mixing a drop of the jelly with a drop of the spermatic fluid directly on a slide and observing under the microscope. We found that complete immobility results in the case of every jelly with this base.

Our tests show that a glycerite of starch base is much inferior in this respect to the Durekol base. The glycerite of starch acts solely as a mechanical barrier.

Since clinical findings are, in the last analysis, more important than laboratory determinations, it is significant that we can state as an undisputed fact that our jellies are not only clinically tested but are used in the majority of American contraceptive clinics.

[This majority does not include any clinics to whom we have given materials without charge.]

The jellies which we produce may be divided as follows:

1. Jellies which are distinctly and rather strongly acid with lactic acid.
2. Jellies which are slightly acid and buffered and depend for effectiveness chiefly on mechanical action.
3. Jellies whose acidity depends on the presence of acid salts which also act as buffers to maintain this acidity during coitus.

*NOTE: It has been the consistent policy of Durex Laboratories, in introducing contraceptive jellies to physicians, to adhere rigidly to the following procedure:

1. The formula is always frankly stated. (Durex Products, Inc., feels it is the physician's undisputed right to know this, since he never prescribes other medicines without such knowledge.)
2. Carefully selected chemicals are subjected to careful analysis to make certain that they have the properties claimed for them. The substances are then tested on fertile, motile spermatozoa. It is a matter of months before all the details are worked out and the resulting substance is ready for clinical tests.
3. Three or more contraceptive clinics then give the jelly a trial and advise Durex Laboratories of their findings. In

addition, physicians with large practices, who are especially interested and cooperative, are given quantities for testing purposes.

4. When this routine has been successfully completed, the jelly is made ready for marketing. Packaging of all Durex products is most conservative.

**NOTE: The quinoline salt found in oxyquinoline sulphate (or chinosol) is but a remote member of the quinine family. Since this is the fact persons having an idiosyncrasy to quinine are not necessarily affected by this quinoline salt. Very often the difficulty will be found in the too generous amount used in a preparation. The oxyquinoline salt is included because of its prophylactic property — not because of its spermicidal value.

4. Jellies which depend on an active spermicidal reagent which is not an acid.

Under heading No. 1 come our jellies LACTIKOL B, CELLIKOL and HEXYKOL B (pat. applied for).

Lactikol B contains

0.05% Chinosol
2.0% Lactic Acid
Durekol Base q.s.
pH — 2.9

It has been found very effective both in laboratory tests and clinically.* Its high acidity (pH value of 2.9) is very effective in destroying spermatozoa.



The presence of oxyquinoline sulphate gives the jelly its antiseptic properties — this material having definite bacteriocidal properties against organisms such as the gonococcus.

Hexykol B contains

2.0% Lactic Acid
0.05% Hexylresorcinol
Durekol Base q.s.
pH — 2.3



The Hexylresorcinol not only gives the jelly decided antiseptic properties, but it also acts to assist the acid content as a spermicide — as Hexylresorcinol is actively spermicidal. It is particularly to be recommended where there is any idiosyncrasy to oxyquinoline compounds so that the less expensive Lactikol B cannot be used.

Cellikol depends for its spermicidal activity on the presence of acetic and lactic acids and Durekol

base. It is buffered with boric acid, its composition being

0.1% Acetic Acid
2.0% Boric Acid
1.0% Lactic Acid
Durekol Base q.s.
pH — 2.8

It may be recommended where the germicidal action of Lactikol B or Hexykol B is not needed, and where there may be some idiosyncrasy toward quinoline compounds.



It is a good spermicide, the acetic acid being particularly effective (1-2,000 solution immobilizing in 10 to 15 seconds).

In Class No. 2, we have only **Lactikol A** which contains

4.0% Boric Acid
0.5% Lactic Acid
Glycerine and Amylum base q.s.
pH — 5.8

It is effective mechanically, acting both as a physical barrier and as an adhesive which entangles and thus immobilizes the sperm.



It is very mild having only a slight acidity. Due to this fact, it may be used in cases where there is considerable laceration of the tissues without serious irritation. However, it should never be recommended without a carefully fitted diaphragm.

*NOTE: Lactikol B Formula is the only one in existence which has been used as a sole method of contraception over a period of time (since 1930) and with an appreciable number of patients (approximately 750) in a recognized American Clinic. But one known failure has been reported. Another experiment of like nature has just recently been embarked upon and again it is Lactikol B which is being employed for the test.

In class No. 3, we have **Tartrikol A**, which contains:

3.0% Aluminum Aceto Tartrate
1.0% Boric Acid
0.05% Chinosol
Durekol Base q.s.
pH — 4.5

The spermicidal effect of this jelly depends chemically on the slightly acid salt — aluminum aceto tartrate. This by hydrolysis furnishes a definite (though low) concentration of acetic and tartaric acids which are very active spermicides.

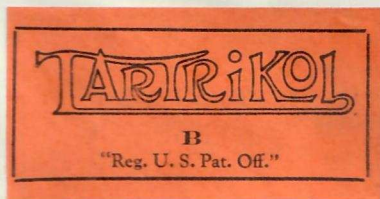


The slightly astringent action of the aluminum aceto tartrate is sometimes desirable in multipara. The oxyquinoline sulphate is desirable as previously explained for its prophylactic value.

This same jelly can be provided with the oxyquinoline sulphate substituted by an equal concentration of Hexylresorcinol for such patients as may be sensitive to quinoline salts.

This jelly is our **Tartrikol B**, which contains:

3.0% Aluminum Aceto Tartrate
1.0% Boric Acid
0.1% Hexylresorcinol
Durekol Base q.s.
pH — 4.5



The low acidity of this jelly is desirable for such patients as are sensitive to the higher acidities of the lactic acid containing jellies — and who need the astringent effect of the aluminum aceto tartrate present.

In class No. 4, we have **Hexykol A**. (Pat. applied for.) Hexykol A contains

0.1% Hexylresorcinol
Durekol Base q.s.
pH—4.5

This jelly depends for spermicidal action on the chemical effect of the Hexylresorcinol. Voge has found that at these concentrations Hexylresorcinol kills sperm very rapidly indeed (1-1,000 immediate immobilization) — and for such cases as are susceptible to either quinoline salts or high acidity, this jelly is without equal.



Its antiseptic properties as well as the fact that it is odorless, colorless and non-poisonous still further recommend it. It has been very effective both in laboratory and large scale clinical tests.

We believe that these formulae we are offering with the one exception of Lactikol A (which we do not feel should be used except with another method unless the known fertility is *low*) may be used alone with as high a percentage of success as Lactikol B.

It is but fair to point out that the "failure" cases are not by any means as likely to be the fault of the product as they are instances of incomplete examination, explanation and *followed out instructions*.

* * * * *

We wish to point out in addition the following facts:

Durex jellies will *not* induce sterility.

They are guaranteed for one year against deterioration.

They are soluble in water.

They are not poisonous.

They have no objectionable odor.

They leave no stain on clothing.

Appurtenances are a most important consideration to physician, pharmacist and patient.

Durex jellies are packaged quietly and conservatively as we feel products of such an intimate, personal nature should be. They create a most favorable first reaction from the discriminating patient.

The literature accompanying Durex jellies is at once dignified and simply phrased.

With the thought constantly in mind that appurtenances are very important, we have shaped our policy to conform with this idea by

a) Using the best type of tube we could purchase to avoid the replacements and unavoidable unpleasantness which would occur through the breaking or splitting of cheap tubes.

b) Furnishing a key to readily regulate the quantity for injection.

c) Supplying a nozzle or applicator long enough (five to six inches) to reach the full length of the vagina. (The application should be made as high up as possible in the vagina.)

The nozzle is thick enough at the tip so that the urethra cannot be entered by mistake.

Although we have always used a glass which would not break or splinter in ordinary use (and certainly not within the vaginal vault), we have recently been employing a nozzle made of a celluloid compound—so that the psychological fear on the part of the patient that it would break might be dispelled. This new nozzle is sterilizable (by boiling) and of course will not break in use. It is transparent like the glass one was and the patient can see when it is filled to the tip or when there is an air spacing for which she should make allowance.

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Volume I

OCTOBER, 1933

Number 4

The Measures or Methods of Contraception as outlined in previous Durex Notes included in Group I.—Methods acceptable to prescribe or recommend. (Largely based on the fact that intra-mural and extra-mural clinics everywhere endorse them.)

1. Diaphragm pessary with contraceptive jelly, described in *Technical Data*.
2. Cervical pessary with contraceptive jelly, described in *Durex Notes No. 2*.
3. Sheath (Condom) with contraceptive jelly, described in *Durex Notes No. 3*.
4. Chemicals alone—in selected cases, (preferably jellies) discussed herein.

Physicians, pharmacists and the laity are for the most part in a state of confusion because of the avalanche of marriage or feminine hygiene preparations flooding the market. The total absence of standardization of any sort or any control of the situation from a recognized medical or pharmaceutical group makes this kind of situation possible.

Among the many products on the market there are probably not more than a dozen that are worth being sold. The formulae vary but slightly in most instances. Generally speaking "the more ingredients, the better the product" seems to be the slogan. The descriptions vary in accordance with the ignorance or aggressiveness of the manufacturer. The prices for the most part fluctuate to meet or lower the quotation of the man who was detailing the physician the "other day". Free goods, consignment, etc. deluge the physician and the pharmacist.

Since contraception is distinctly a medical matter, the resultant chaotic state is, naturally, a cause for concern to the physician. Both physician and pharmacist should cooperate with the reputable manufacturer in an effort to protect a gullible laity.

It has only recently been possible (and manufacturers do not yet have the means at their disposal) to reproduce the condition existing in the vaginal vault during or after coitus. Without a simple and effective method of determining the acidity of the vaginal vault of a given patient, the manufacturer cannot supply a product which can be guaranteed under all conditions to kill spermatozoa in the vault, even though the ingredients kill instantaneously on the slides or in the test tubes in the laboratory. The normal acidity of the vaginal canal is approximately pH 4.1. What the conscientious manufacturer has done and can do is to accept what bio-chemistry states to be the norm and develop his product accordingly.

The Use of the Chemical Contraceptive

The use of chemicals alone as a contraceptive measure is a most controversial matter among physicians.

It is logical that laboratory results with live sperm are an excellent indication of the efficacy of a chemical but clinical findings (and experiments) are the final test.

This fact granted, the next consideration is whether

1. The blocking (by an impenetrable film) of the cervix is more important than
2. The immediate or almost immediate immobilization of the sperm.

The combination of the two is not only possible in most instances, but also proportionately more effective. (This is possible where the viscosity of the base is sufficiently high to have some barrier action and to avoid the tendency to liquefy unpleasantly at body temperature and at the same

The type or form of chemical to be employed is important. The following table has been prepared to indicate the properties, advantages and disadvantages of each of the five forms of contraceptive material which depend for their efficacy upon the action of chemical substances.

Type of Chemical	1. Suppository a) cocoa butter b) boro glycerin	2. Foam or effervescent tablet	3. Powder (sprayed into vault)	4. Foam jelly	5. Jelly
Form	Conical or spherical masses packed in boxes	Large round pellets in cylindrical glass tube	Powder packed in jars	Two solutions in double tube (one inside the other)	Solution in collapsible tube (sometimes in jars)
How inserted	By hand	By hand	With use of atomizer or blower	With use of nozzle	With use of nozzle or plunger device

ADVANTAGES

Suppository	Foam Tablet	Powder	Foam Jelly	Jelly
Easily carried.	Easily carried.	If evenly dispersed and dissolved in vagina will serve as barrier.	Independent of time Independent of moisture Independent of temperature.	Independent of time Independent of moisture Independent of temperature
Easily placed by anatomically informed person.	Easily placed by anatomically informed person.	Can be water soluble.	When properly compounded will serve as barrier. (Proper viscosity).	When properly compounded will serve as barrier. (Proper viscosity).
Type (a) simple to compound.			Possibility of double spermicidal action.	Possibility of double spermicidal action.
Simple to purchase.			Can be used as lubricant with other methods.	Can be used as lubricant with other methods.
Lacks appurtenances.	Lacks appurtenances.		If properly compounded will not disintegrate.	If properly compounded will not disintegrate.
If properly compounded melts at body temperature.	Odorless.	Odorless.	Can be water soluble.	Can be water soluble.
If properly compounded will not deteriorate.	If properly compounded will not deteriorate.	If sealed well, will not deteriorate.	Can be stainless.	Can be stainless.
	Does not cause dripping.		Nozzle or plunger provides easier and deeper injection most necessary for patient with short fingers and long vault. Also assures proper spreading of substance despite lack of anatomical knowledge.	Nozzle or plunger provides easier and deeper injection most necessary for patient with short fingers and long vault. Also assures proper spreading of substance despite lack of anatomical knowledge.
			Can possess advantages of low surface tension.	Can possess advantages of low surface tension.

DISADVANTAGES

Suppository	Foam Tablet	Powder	Foam Jelly	Jelly
Dependent on time.	Dependent on time.	Dependent on time.	More bulky to carry.	More bulky to carry.
Dependent on temperature.	Dependent on temperature.			
Not water soluble.	Not always water soluble.	Dependent on moisture.		
Annoyance from subsequent dripping.	Dependent on moisture.	Prone to cake or lump.		
Fats or oils contained therein soil clothing.	Dependent on pressure.	Even dispersion not likely unless air distends vaginal walls.		
Odor in type (a) objectionable.		More bulky to carry.	Appurtenances necessary.	Appurtenances necessary.
Low temperature necessary to keep when not in use.		Appurtenances necessary.		
Psychological uncertainty (no way of determining if suppository has melted).	Psychological uncertainty (no way of determining if tablet has effervesced).	Psychological uncertainty (no way of determining if powder has dissolved or dispersed).		
Psychological deterrent in necessary delay.	Psychological deterrent in necessary delay.	Psychological deterrent in necessary delay.		
Type (b) if sufficiently stable to handle, melts slowly; otherwise, melts easily, but becomes sticky, making insertion difficult.				
Injures and eventually rots rubber.				
Dependent on occlusive properties principally, since chemical action is interfered with by presence of fats and oils.				
Cannot be used as lubricant with other methods.	Cannot be used as lubricant with other methods.	Cannot be used as lubricant with other methods.		

time, the surface tension is sufficiently low to cause thorough penetration of the active ingredients into the minute interstices of the surfaces of the vaginal tissue.) The base is a most important and often overlooked factor.

As in the case of other methods of contraception, no physician should employ a chemical method without first

- a) making a thorough pelvic examination preliminary to prescribing or recommending the given method,
- b) giving careful, detailed anatomical instruction to the patient,
- c) supplying precise directions for each case.

If the physician does not adhere to the procedure outlined above he cannot conscientiously prescribe or recommend the method (without any other contraceptive aid) unless he *subscribes to the following general considerations*:

1. The case in which fertility is below average.
2. The case of a nullipara (with uterus in position).
3. The case of a patient unable to use any other accepted method.

It is fair to emphasize one fact which physicians and the laity are prone to lose sight of—namely, that unless scientifically and prudently *prescribed and used*, the best possible product will not prove effective. In short, the “failure” cases are not as likely to be caused by faulty products as they are to be caused by incomplete examination, information and followed-out instructions.

In summary of the table on the foregoing page may we point out these facts:

- a. The merits of the suppository are vitiated to a great extent because they are so dependent upon the temperature of the body.
- b. The merits of the foam tablets are vitiated to a great extent because they are so dependent on sufficient moisture* being present in the vagina.

*The small amount of moisture present in the vagina ($\frac{1}{2}$ to 1 c.c.) has to be depended upon to start action of foaming. (Manufacturers themselves suggest the addition of 1 c.c. of water to a tablet in a test tube for demonstration purposes.) After coitus, the fluid content of the vagina is approximately 4.0 c.c.. To be successful the moisture present in the vagina should be sufficient to cause reaction so that a barrier is formed before the ejection of the male semen takes place.

c. The merits of the powder are likewise vitiated because they are dependent on sufficient moisture.

d. The disadvantage of apparatus in the foam jelly is a negligible consideration since its possibilities of success are so many. The fact that the American foam jelly is not satisfactory** does not mean that the principle is wrong.

e. The disadvantage of essential apparatus in the use of the jelly does not negate the decided advantages of its ability to act both as barrier and spermicide.

Certain types of cases are especially adapted to the use of one or more of these chemical substances. The decision rests with the physician himself as to the best type to recommend.

The progressive manufacturer is prepared to experiment and work with clinics and physicians to obtain the preparation best suited to the majority of cases. It is well for medical groups to recognize the fact that there are some manufacturers who have standards and ethics and are not looking upon this field as one to be exploited.

CONTRACEPTIVE JELLIES have in general percentage ratings from 85 up to 100 per cent—when used alone. These percentages vary with the actual type of jelly used and the care with which examination, instruction and followed-out instruction are adhered to. The percentage of success may be extremely high when all conditions are favorable. Dr. Robert L. Dickinson, in his work “Control of Conception” states—“Irving Stein, in the Mandel Clinic in Chicago followed up over a hundred patients using a jelly with chinosol and lactic acid and reports complete protection for over one year for all patients who persisted in following directions exactly.”

More recently (June 1, 1933) Dr. Stein has unofficially advised: “I wish to state that we have been using —, both in the clinic and in my private practice since we completed the investigative work a few years ago.

“I am not sure of the number of patients on whom it has been used but I would estimate some-

**Re-American Foam Jelly—“The viscosity of this would appear to be, however, too high and the foaming capacity is in my opinion, low and insufficient since it only occurs after considerable mixing of the constituents.” — Voge—The Chemistry & Physics of Contraceptives—p. 192.

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If he is one of the few not stocking DUREX the makers name and address will be supplied on application by the Chemist to his Trade Journal.