

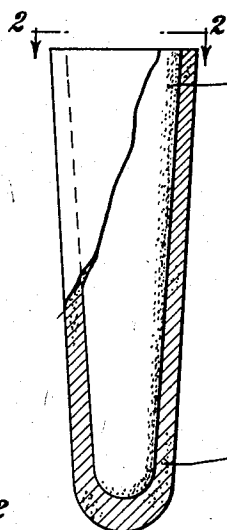
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R. D. HETTERICK
DUAL ELEMENT SUPPOSITORY

2,696,456

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Fig. 1



10 - OIL-SOLUBLE WATER-INSOLUBLE CORE:
EMOLLIENT BASE (COCA BUTTER ETC.);
HEALING AGENT (BALSAM OF PERU);
ETC.

12 - WATER-DISPERSIBLE COATING:
WATER-DISPERSIBLE BASE (A GLYCOL FATTY
ACID ESTER, ETC.);
MILD, QUICK, LOCAL ANESTHETIC;
GRANULATION AGENT (UREA);
ETC.

Fig. 2

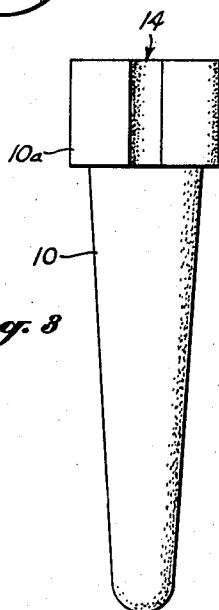
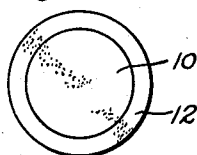


Fig. 3

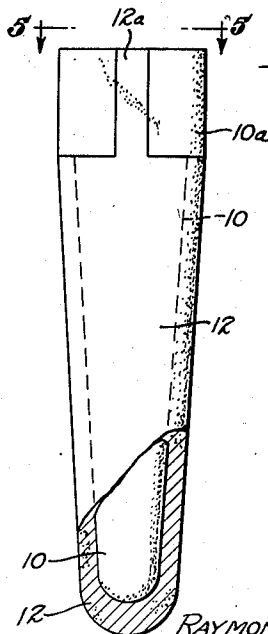
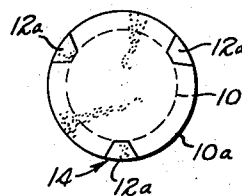


Fig. 4

Fig. 5



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DUAL ELEMENT SUPPOSITORY

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3 Claims. (Cl. 167—64)

This invention relates to suppositories adapted particularly for the treatment of hemorrhoids and conditions involving anal and similar abrasions and disturbances.

An object of the invention is to provide for the medical profession a suppository capable of making effective immediately a local anesthetic to reduce to a minimum any discomfort of introduction, and to make quickly effective the action of medicaments and emollient materials appropriate for promoting healing effects. An incidental object is to render the indicated anesthetic effects and action of the medicaments and emollient materials very much more rapid than has heretofore been possible.

It is another object of the invention to provide a suppository consisting essentially of two elements, one of which is an outer coating containing a mild local anesthetic in a carrier which disperses very rapidly in the body fluids so as to make the anesthetic material and medicaments immediately effective, and the other of which is an inner core which in turn provides for dispersion of healing emollient and other medicament materials, contained therein, immediately following dispersion of the coating material.

It is additionally an object of the invention to provide in such a suppository a water-dispersible coating containing the indicated anesthetic, the coating being readily dispersible in body fluids, and a water-insoluble, oil-soluble core which melts readily at body temperatures and carries the indicated medicaments and healing agents.

Heretofore suppositories in general have been produced as a single unit containing oil-soluble and water-soluble materials in an oleaginous base. The suppositories have been found objectionable because of the adverse distribution coefficient between the oleaginous base and the aqueous fluid of the mucous surface of the area to be treated, the availability of the water-soluble constituents being reduced because the oleaginous constituents occlude the absorptive surfaces of the mucous membranes.

It has also been found that many common therapeutic agents employed in the formulation of ordinary suppositories, particularly such insoluble compounds as zinc and bismuth salts, increase the viscosity of the oleaginous bases, thereby preventing ready liquefaction of the mass in the body orifice with the result that the medicaments may not be released, but may be held in the agglomerated mass of the suppository and may, therefore, be excreted without exerting the desired therapeutic effect. When the drugs or medicaments are incorporated in a water-soluble base type suppository, the demulcent and emollient action of the cocoa butter usually present is sacrificed, and the value thereof as an adjunct is thus limited.

However, the physio-chemical vehicle-medicament relationships as applied in the present suppository result in one which releases the medicaments to the tissues in proper sequence and the disadvantages and objections of the conventional types are overcome.

Other objects of the invention and the various features thereof will become apparent to those skilled in this art upon reference to the following specification and accompanying drawing wherein certain embodiments of the invention are disclosed.

In the drawing:

Fig. 1 is a view partly in vertical section and partly in elevation showing a coated suppository embodying the improvements hereof and indicating principal constituents both of the core and of the coating;

Fig. 2 is a top plan view of the suppository of Fig. 1 as indicated by the line 2—2 of Fig. 1;

Fig. 3 is an elevation of a slightly modified form of core;

Fig. 4 is a view partly in vertical section and partly in elevation of a completed suppository containing the core of Fig. 3; and

Fig. 5 is a plan view of the suppository of Fig. 4.

With particular reference to the drawing, the suppository of this invention comprises a conical core 10 of a composition presently to be described, and having its conical face covered with a coating 12 of a composition also presently to be described. As seen in Figs. 2 and 5 the core is a solid core, i. e., free from cavities. The tip of the coating 12 is preferably thickened somewhat so that the thickness thereof approximates about twice the thickness of the average coating applied directly to the conical wall of the core 10. Desirably, the coating 12 steadily reduces in thickness as it extends from its tip to the base of the suppository, although a coating which is of uniform thickness between the tip and the base of the core is within the scope of the invention. The increased thickness at the tip of the conical structure compensates for increased time of contact of the tip with the body membranes of the patient as the suppository is introduced, and provides for an adequate supply of anesthetic and other agents of the coating in order to insure quick action thereof throughout the extent of the body parts being treated.

In the form of the suppository of Figs. 3, 4, and 5, the core 10 is provided with a flanged base portion 10a whose frusto-conical walls are exposed and lie flush with the outer conical coating 12. Preferably, where the base portion 10a is employed, its outer frusto-conical wall is provided with one or more longitudinally extended grooves 14 which, when the coating 12 is applied, are filled with integral extensions 12a of coating material. This arrangement facilitates application of the coating 12 to the core 10, and also provides a modicum of coating material at the locus of the core base 10a.

Principally, the coating 12 comprises a water-dispersible base which is solid at normal room temperatures and completely disperses at body temperatures in the presence of body fluids. Such a water-dispersible base is desirably a glycol fatty acid ester, such as polyethylene glycol stearate, or the like, as more fully set out below. An essential agent contained in this outer coating 12 is a mild, nonirritating, noninjurious, quick acting local anesthetic, of which propyl p-amino benzoate is the presently preferred form.

Another very desirable agent to be employed in the coating is a tissue granulating agent of which urea is the presently preferred form.

An acceptable composition for the outer coating, at least for some purposes, is as follows:

Polyethylene glycol stearate, approximately 95% to 99%
Propyl p-amino benzoate, approximately 1% to 5% (for example 2%).

An improved coating will contain about 1% to 5% of a tissue granulation agent, such as urea, for example 2.5%, above indicated. This will replace a corresponding proportion of the glycol stearate.

As has been indicated above, by using a water-dispersible coating base, such as the indicated glycol stearate or an equivalent glycol fatty acid ester, or the like, the anesthetic material becomes immediately effective because the coating composition begins to disperse in the aqueous fluid of the mucosa immediately upon application of the suppository coating thereto. Similarly, where the tissue granulation agent is used, this also becomes immediately effective because of the water-dispersible character of the coating. Obviously both the anesthetic and the tissue granulation agent are adequately water-soluble to result in the desired immediate effect.

In the event that a mechanical protective coating effect is desired, as is commonly the case, an agent such as bismuth subgallate may be employed for this purpose, this material being appropriately used in percentages between about 3% and about 8% of the composition, for example 5%, corresponding proportions of the glycol stearate being replaced thereby. Similarly, should an astringent be required, as is commonly desirable, zinc

oxide, which also possesses antiseptic properties, may be used. An appropriate proportion of zinc oxide would be about 10% or between about 5% and 15%. It is also desirable when zinc oxide is used that the proportion of the glycol stearate be correspondingly reduced.

In practical use, it has been found clinically desirable to incorporate a minor but adequate proportion of an antiseptic material which has local bactericidal action and will inhibit contamination. One very satisfactory and preferred agent for this purpose is N-lauroyl colamino formylmethylpyridinium chloride which may be used in an amount between about 0.05% and 0.5%, for example, 0.1%.

Substitutes which are usable, at least for some purposes, for various coating constituents above mentioned will be discussed more fully hereinafter.

As to the polyethylene glycol stearate employed, the term is intended to include any such ester having a molecular weight in the order of 1,000 to 4,000, or those which tend to contain 10 to 40 ethylene groups. In general, for the coating composition such glycol ester should be one having a melting point ranging between about 40° C. and 60° C., although the melting point of the coating, so long as it is high enough to withstand storage temperatures, is not critical because of the fact that even these higher melting-point esters disperse readily in the aqueous fluids of the human body. Commonly a polyethylene glycol stearate having a molecular weight in the order of 1,000 to 1,500 is employed.

With respect to the composition of the suppository core, this is made up of an emollient material having an appropriate melting point, namely, about 35.5° C., so that it is solid at normal room temperatures but will melt at body temperatures. This emollient preferably consists of or predominates in cocoa butter. When required to raise the melting somewhat, white beeswax is added in appropriate proportion. Ordinarily the dominating constituent of the core in addition to the emollient cocoa butter is balsam of Peru which is used to stimulate healing. Balsam of Peru may be employed in varying amounts between about 1% and 5% or 6%, for example 3%, the remainder of the composition being the emollient material such as cocoa butter. In other words, the core may consist of about 97% cocoa butter and 3% of balsam of Peru. However, it is ordinarily desirable, if not necessary, to include an agent to solubilize the balsam of Peru in the cocoa butter. This agent may be the water-dispersible glycol fatty acid ester above mentioned. Where 3% of balsam of Peru is employed, approximately 3% of the glycol ester is used, this varying between about 0.5% and 5% as the balsam varies. Addition of this material correspondingly reduces the emollient cocoa butter content. Thus, acceptable core compositions, at least for some purposes, are within the following:

Balsam of Peru approximating 1.0% to 5% or 6%.
Solubilizer approximating 0.5% to 4% or 5%.
Emollient vehicle (cocoa butter) approximating 98.5% to 90%.

If required or deemed necessary, small proportions of cod-liver oil may be used to provide an additional healing emollient. Thus, about 2.5% of cod-liver oil, or between about 1% and 5% or 6% may be added, the cocoa butter emollient being correspondingly reduced. In this case it may be desirable to add beeswax to raise the melting point of the core. Thus, to obtain the above-indicated melting point of 35.5° C., beeswax in the neighborhood of 15% to 30% is desirably employed.

More specifically, a preferred core having a melting point of 35.5° C. has had the following composition (optimum ranges also being given):

	Range percent
Balsam of Peru approximating 3.0%-----	1.0 to 5
Polyethylene glycol stearate (solubilizer for balsam of Peru) approximating 2.0%-----	0.5 to 4
Cod-liver oil (healing emollient) approximating 2.5%-----	1.0 to 5
Beeswax approximating 17.5%-----	15.0 to 30
Cocoa butter approximating 75.0%-----	87.5 to 96

In combination with a core having a melting point of 35° C. to 36° C., as above indicated, a very effective coating having an appropriate melting point (e. g. 45° C. to 50° C.) is the following (optimum range also given):

N-lauroyl colamino formylmethyl-pyridinium chloride (antiseptic) approximating 0.1%--	0.1 to 1
Propyl p-amino benzoate (anesthetic) approximating 2.0%-----	1.0 to 5
Urea (tissue granulation agent) approximating 2.5%-----	1.0 to 10
Bismuth subgallate approximating 5.0%-----	2.5 to 8
Zinc oxide (astringent) approximating 10.0%--	5.0 to 10
Polyethylene glycol stearate (water-dispersible base) approximating 80.4%-----	90 to 96

In using the above coating and core compositions, it will be apparent that the water-dispersible coating first disperses in the body fluids and makes the anesthetic and also the tissue granulation agent, if used, immediately effective. Similarly, any other of the above-mentioned coating agents, if used in the coating, become promptly effective. After dispersion of the coating, the water-insoluble core material then begins to melt, so that the balsam of Peru or similar healing agent becomes promptly effective along with the melted emollient cocoa butter with or without cod-liver oil or the like.

Where a water-dispersible agent is used in the coating which is appropriate to solubilize the balsam of Peru, such a water-dispersible base acts also partially to emulsify the emollient materials of the core at the time the core melts, whereby the core readily releases its medicaments in the dispersion medium which resulted from the liquefaction of the outer coating.

From the standpoint of materials which may be employed, at least for some uses, as substitutes for the much preferred agents above discussed, the following data are given.

In the outer coating, as has been pointed out above, the highly preferable water-dispersible base is polyethylene glycol stearate. Substitutes, as above indicated, may be polyethylene glycol oleate and laurate, ethylene glycol stearate, diethylene glycol stearate, glycerine monostearate, other stearic acid esters of glycerine, glycols or polymerized glycols, glycerine or glycol esters of other fatty acids than the stearic, oleic, and lauric acids above mentioned, such as palmitic, myristic, and similar fatty acids, derivatives of polyalkylene oxides, combined with castor oil, ricinoleic acid, oleyl alcohol, or the like, such as propylene oxide, ethylene oxide and similar cyclic oxides, or organic esters of polyhydric alcohols, such as mannitol, sorbitol, and dulcitol, or their anhydrides, such as mannitan, sorbitan and dulcitan. If required, the coating base may contain other appropriate emulsifying agents such as triethanolamine, triethanolamine stearate, sodium or potassium stearate, stearates of ethylamine and diethylamine, and monoethanolamine and diethanolamine stearates, palmitates, and oleates.

From the standpoint of the anesthetic, this must be nonirritating upon application, must create anesthesia without damage to nerve structure, must have a low systemic toxicity, and must possess rapidity of onset of anesthesia. While the above-mentioned propyl p-amino benzoate is the highly preferred anesthetic for use in these suppositories, nevertheless, it is sometimes adequate to use one or more of the following: benzocaine (ethyl p-amino benzoate), isobutyl p-amino benzoate, laurocaine, procaine, phenacaine (holocaine), nupercaine, ephedrine, butacaine, tutocaine, and saligenin. These materials are employed in their respective appropriate forms including the sulfates and hydrochlorides, as the case may be. Where butacaine sulfate, tutocaine hydrochloride, and holocaine are employed, it will be necessary, due to insolubility in the coating material, to disperse them in the molten coating and maintain even dispersion thereof during production of the suppository.

With reference to the antiseptic which may be used in the coating, the preferred material is the quaternary ammonium compound N-lauroyl colamino formylmethylpyridinium chloride, previously mentioned. However, it is possible to use other quaternary ammonium salts, such as cetyl trimethyl ammonium bromide, octadecenyl dimethyl benzyl ammonium bromide, p-tert-octylphenoxy ethoxy ethyl dimethyl benzyl ammonium chloride, 4-sulfonamidobenzyl tetradecyl dimethyl ammonium bromide. For appropriate uses one or more of the following may be employed: phenol, potassium resorcin sulfonate, secondary amyltricsols, organic mercurials, oxyquinoline benzoate, ethyl m-amino p-hydroxybenzoate, hydroxy-

quinoline bases such as iodochlorohydroxyquinoline, and the like.

As above indicated, bismuth subgallate is a preferred bismuth compound providing a mechanical protective-coating action, but other bismuth compounds often may be used such as bismuth subiodide, bismuth iodotannate, and bismuth resorcinate. Where zinc oxide has been mentioned as a preferred mild astringent, it sometimes will be acceptable to employ tannic acid, hamamelis, nutgall, extract of belladonna, alum, and aluminum acetate. Where urea has been particularly mentioned as the preferable stimulating agent for tissue granulation, it may sometimes be acceptable to substitute allantoin, ichthammal or kindred tissue granulation stimulating agent.

In the core, cocoa butter has been employed as the principal core vehicle because of its emollient properties, and, as has been pointed out above, a small amount of cod-liver oil may be added, if desired, because of its emollient and healing action, beeswax being added in whatever amount is required to establish the desired melting point of around 35.5° C. In order to increase the area of contact and increase the drug exchange between fluids of the mucosa and both the soluble and insoluble drugs a small amount of emulsifying agent has been added to allow for greater amounts of liquid to become incorporated in the mass. As previously pointed out, around 1% of polyethylene glycol stearate has been added to the core, thereby performing both the action just mentioned and solubilizing the balsam of Peru. Other emulsifying agents which might be used for this purpose, but are usually less desirable, are triethanolamine stearate, glycerol monostearate, the sulfonated ester of dicarboxylic acid known as Aerosol OT, and Lanette wax SX, a British product which is a mixture of the higher fatty alcohols derived from the higher fatty acids by splitting oil, such as whale or coconut oil, the higher fatty alcohols being then sulfated (the S meaning sulfated and the X meaning 10% sulfated alcohol present).

The use of both cod-liver oil and balsam of Peru in the indicated amounts supplies to the suppository the healing effects of both of these agents. If desired, a small amount of castor oil, for example about 2%, may be used as a means for solubilizing the balsam of Peru, these being combined before incorporation into the core mass. By this means the balsam of Peru is prevented from separating out. Otherwise, the above-mentioned small proportion of polyethylene glycol stearate may be used alone or in addition to the castor oil.

Respecting balsam of Peru, which is used because of its ability to stimulate local resistance in the tissues and a tendency to exert a protective action, as well as a mild bactericidal action, no wholly satisfactory substitute has been found, but partial satisfaction may be obtained from balsams of tolu, benzoin and storax, myrrh and tyrothricin. Substitutes sometimes usable instead of beeswax are paraffin (about 50° C. M. P.), spermaceti, carnauba wax, ceresin, ozokerite and polyethylene glycols having higher molecular weights in the range from about 1,500 to 4,000 with melting points of about 40° C. to 60° C., together with previously indicated esters of such glycols.

In the light of the above outline of various compositions of the inner core and the outer coating, a general range of the various materials indicated in each element of the suppository may be approximately as follows:

OUTER COATING

Antiseptic, approximately 0% to 0.4%, e. g. 0.1%.
Anesthetic, approximately 1% to 5.0%, e. g. 2.0%.
Tissue-granulation stimulant, approximately 1% to 10.0%, e. g. 2.5%.
Bismuth protective-coating compound, approximately 0% or 2.0% to 10.0%, e. g. 5%.
Mild astringent (e. g. zinc oxide), approximately 0% or 5.0% to 15.0%, e. g. 10%.
Water-dispersible base, approximately 65% to 98%.

INNER CORE

Solubilizer, approximately 0.5% to 5%, e. g. 3.0%.
Cod-liver oil, approximately 0.0% to 5%, e. g. 2.5%.
Balsam of Peru, approximately 1.0% to 5%, e. g. 3.0%.
Beeswax, approximately 0.0% to 30%, e. g. 17.5%.
Cocoa butter, approximately 98.5% to 65%.

Expanding on the function of the two parts of the present suppository, the purpose, as has been pointed out here-

tofore, is first to prepare and treat the mucosa and thereafter further to treat the mucosa by a somewhat different type of composition. In the treatment of hemorrhoids and anorectal conditions, various painful conditions commonly exist such as abrasions, traumatism of the mucosa of the canal, minute breaks in the vein walls, or spongy and granular conditions of the mucosa, even to the extent that laceration may exist and ulceration occur in the presence of infective flora. It is desirable, therefore, to cause the suppository to alleviate the pain of introduction under conditions such as above indicated, and prepare the surfaces for treatment by further medicaments, whereby successive therapeutic effects are obtained because of specific characteristics of the successively available agents.

It is also desirable to employ a mild astringent, such as the zinc oxide and similar materials previously mentioned, and also to use one of the bismuth compounds to provide the mechanical protective-coating action mentioned. However, employment of substances such as zinc oxide and the bismuth compounds tends to raise the melting point of the water-insoluble emollient material, such as cocoa butter, required. It is therefore an important feature of this invention that the zinc oxide or other astringent and the bismuth compound are carried in the water-dispersible base of the outer coating which also carries the anesthetic and the antiseptic when used. Thus, not only is the local topical anesthetic effective in the coating to allay pain and to relax the sphincter spasm, when the easy passage of stools is sought, but the astringent and protective-coating materials are made available in the quickly liquefiable water-dispersible coating material without the possibility of having any effect upon the melting point of the core material. Further, by the incorporation of the anesthetic in the water-dispersible base of the coating, a controlled mild surface anesthesia is created which relieves the pressure pain often caused by venous engorgement aggravated by inflammatory reaction of irritated sensory nerve endings. By the prompt action of the anesthetic upon the nerve endings through rapid dispersion of the water-dispersible coating, the anesthetic affords the aggravated tissues the opportunity to retrogress to approximately normal and thereby prepares the surfaces for the emollient action of the medicated core which subsequently melts at the body temperatures. Liquefaction and dispersion of the water-dispersible coating and its medicaments take place very quickly in the anorectal canal so that the anesthetic and any other ingredients present come immediately into contact with the mucosal surfaces. Such immediate release of the mild local anesthetic in the coating almost immediately reduces the discomfort of insertion. Upon exposure of the core following liquefaction of the coating, the demulcent emollient and healing medicaments of the low-melting-point oleaginous core likewise become readily available to the tissues, especially since a degree of emulsification occurs when the core melts and releases its ingredients in the dispersed medium which resulted from the liquefaction of the coating material.

In addition to the preferred forms of suppositories, both with respect to the cores and the coatings thereof, as outlined above, another aspect is found in the fact that the coating may be employed only for a fast-acting, pain-relieving action, and the core employed only for an emollient action. In such a case, the core may consist only of cocoa butter or cocoa butter with other emollients mentioned, and the coating may consist only of the water-dispersible esters mentioned, such as the indicated polyethylene glycol stearate having a molecular weight around 1,500, and containing an appropriate anesthetic. Thus, for rapid anesthetic action the coating would contain about 2% of the mentioned propyl p-amino benzoate where prolonged effect is not required or as much as 5% of such anesthetic when a prolonged effect is necessary. For such uses suppository compositions may be tabulated as follows:

CORE

	Percent
Cocoa butter (with or without other emollients) --	100

COATING

	Percent
Anesthetic (e. g. propyl, p-amino benzoate) --	1 to 5
Polyethylene glycol stearate -----	99 to 95

Thus, the suppository of this invention is safe for use as a palliative and for adjunctive treatment even for rela-

tively long periods of time, as in the case of hemorrhoids and other disturbances amenable to suppositorial treatment.

In addition to the above reference to broader aspects of the invention, other types of suppositories may be produced which also rely upon the water dispersible character of the coating and the water-insoluble, oil-soluble, emollient characteristic of the core. These are represented by a sedative type, an analgesic type, a vaginal type, a nasal type, and a digitalis type. With respect to each of the above, the following exemplary formulae for cores and coatings are given:

Sedative type suppository

This type of suppository may be employed where a quick-acting sedative is required followed by a prolonging effect from a slower acting sedative. For this purpose a water-soluble substance is placed in the coating and a solvent-soluble type incorporated in the core, thus allowing a synergistic action to take place between the two.

Coating:	Percent
Pentobarbital sodium -----	approximately-- 3
Polyethylene glycol stearate -----	do----- 97
Core:	
Phenobarbital -----	do----- 5.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 77.0

Analgesic type suppository

Coating:	Percent
Morphine hydrochloride (or sulphate) -----	approximately-- 1
Polyethylene glycol stearate -----	do----- 99
Core:	
Morphine alkaloid -----	do----- 1.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 81.0

Vaginal type suppository

Coating:	Percent
Lactose -----	approximately-- 25
Urea -----	do----- 10
Phenylmercuric sulfathiazole -----	do----- 10
Polyethylene glycol stearate -----	do----- 55
Core:	
Menthol -----	do----- 2.0
Cod-liver oil -----	do----- 2.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 78.0

Digitalis suppository

Coating:	Percent
Digitoxin -----	approximately-- 0.1
Polyethylene glycol stearate -----	do----- 99.9
Core:	
Digitalis leaf -----	do----- 5.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 77.0

Nasal suppository

Coating:	Percent
Tyrosine -----	approximately-- 6
Polyethylene glycol stearate -----	do----- 94
Core:	
Ephedrine -----	do----- 0.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 82.0

In all of the above specific formulations, it will be noted that incorporated in the coating material are the quick-acting, water-soluble medicaments and in the oleaginous core are placed the medicaments which yield either prolonged action or demulcent effects, or sustain the mode of therapy used.

From the foregoing it will be apparent that I have presented a novel type of suppository for many uses, which, in its broadest aspect relies on a water-dispersible coating adapted to carry various medicaments for initial effect upon the mucosa, and a water-insoluble emollient core adapted to carry various medicaments, which may be subsequently dispersed or solubilized by the agency of the dispersed coating, whereby the emollient and/or medicament effects of the core become effective following the initial effect, such as an anesthetic effect, of the coating.

Inasmuch as modifications of the generic invention herein disclosed will no doubt occur to those skilled in this art, it is intended to protect all such variations as fall within the scope of the patent claims.

I claim as my invention:

1. A suppository comprising: a water-insoluble core which is solid at normal room temperatures and melts at normal body temperatures, said core comprising:

	Percent
Balsam of Peru -----	approximately-- 3.0
Polyethylene glycol stearate -----	do----- 2.0
Cod-liver oil -----	do----- 2.5
Beeswax -----	do----- 17.5
Cocoa butter -----	do----- 75.0

and a coating upon said core, said coating being solid at normal room temperatures and being dispersible in body fluids, said core comprising:

	Percent
N-lauroyl colamino formylmethyl-pyridinium chloride -----	approximately-- 0.1
Propyl amino benzoate -----	do----- 2.0
Urea -----	do----- 2.5
Bismuth subgallate -----	do----- 5.0
Zinc oxide -----	do----- 10.0
Polyethylene glycol stearate -----	do----- 80.4

2. A suppository comprising: an outer coating; and an inner core, said coating and core having respectively approximately the following compositions:

Outer coating:	Percent
Antiseptic -----	approximately-- 0.5 to 1
Anesthetic -----	do----- 1 to 5.0
Tissue-granulation stimulant -----	do----- 1 to 10.0
Bismuth protective-coating compound -----	do----- 2 to 10.0
Mild astringent -----	do----- 5 to 15.0
Water-dispersible base -----	do----- 65 to 98.0

Inner core:	
Solubilizer -----	do----- 0.5 to 5
Cod-liver oil -----	do----- 1 to 5
Balsam of Peru -----	do----- 1.0 to 5
Beeswax -----	do----- 15 to 30
Cocoa butter -----	do----- 98.5 to 56

3. A suppository comprising: a core consisting essentially of a water-insoluble oily base which is solid at normal room temperatures, melts at body temperatures, and comprises an emollient vehicle and a medicament carried in said vehicle; and an outer coating upon said core, said coating being solid at normal room temperatures, and dispersible at body temperatures in the body fluids, said coating comprising a water-dispersible material which is also a dispersion agent for said oily base, said material consisting of a higher fatty acid ester of a polyhydric alcohol and being present in sufficient quantity to substantially completely disperse all of the oily base of said core.

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