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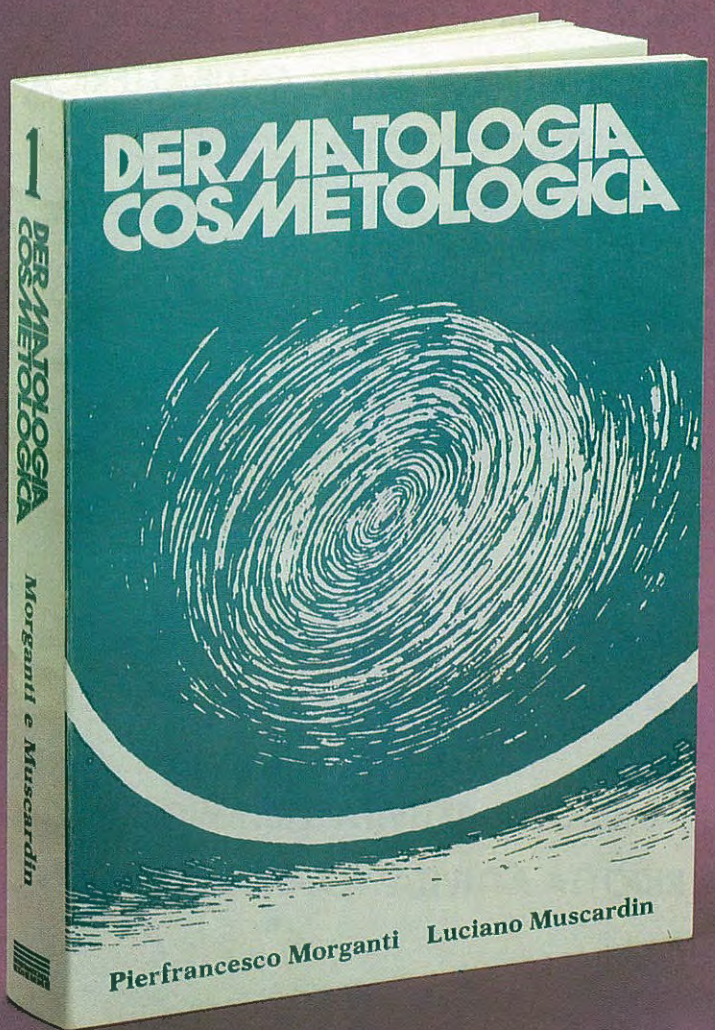

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Contents

Original Laboratory Studies

General Articles

XIX Announcements

5th WORLD CONGRESS OF THE INTERNATIONAL SOCIETY OF COSMETIC DERMATOLOGY
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38TH CONGRESS OF THE GERMAN DERMATOLOGICAL ASSOCIATION
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LONG-TERM EFFECTS AFTER TOPICAL APPLICATION OF ACTIVE RETINYL PALMITATE.

Erling Thom
Ph.D., Medstat Research Ltd., P.O. Box 210, N-2001 Lillestrøm, Norway.

Received: *June 29, 1994*

Key words: *Retinyl palmitate, skin penetration, skin thickness, skin elasticity, long-term effect.*

Synopsis

A randomised double-blind within subject study comparing two galenical formulations of retinyl palmitate (RP), a conjugated and an unconjugated one, showed significant differences in favour of the conjugated formulation with respect to improvement in objective and subjective skin parameters on the volar part of the forearms. The treatment period was 3 months, and 20 female subjects took part in the study. In order to study the duration of the effect, objective measurement of skin elasticity and thickness as well as subjective evaluations by the subjects, were repeated 12 months after cessation of treatment. The results of the study show, as can be expected, that improvements in skin parameters will vanish over time. However, after treatment with the active formulation, still about 25% of the improvements in the objective skin parameters obtained after a treatment period of 3 months are detectable after a 12 month treatment-free period. These results indicate that less frequent administrations of active RP can be used during maintenance treatment.

Riassunto

Con uno studio randomizzato a doppio ceco sono state controllate differenti formulazioni galeniche di retinolo palmitato (RP) in forma libera e coniugata.
I risultati ottenuti hanno dimostrato differenze significative a vantaggio della forma coniugata con le diverse metodiche utilizzate sia soggettive che obiettive. Il periodo di trattamento si è protratto per tre mesi con un gruppo composto da 20 volontari di sesso femminile.
Per valutare la durata dell'effetto dodici mesi dopo l'interruzione del trattamento è stata verificata sia l'elasticità e lo spessore della cute mediante l'utilizzo di metodiche obiettive che l'aspetto generale della pelle mediante valutazioni soggettive. Come si prevedeva la maggior parte dei miglioramenti ottenuti sui diversi parametri cutanei si vanifica con il trascorrere del tempo.
Comunque, dopo trattamento con la formula attiva il 25% circa dei miglioramenti ottenuti permangono anche dopo 12 mesi dall'interruzione.
Questi risultati indicano che possono essere utilizzate applicazioni meno frequenti dell'attivo RP durante il periodo di mantenimento.

Introduction

Treatment of the human skin with water solubilized retinyl palmitate (RP) ointment for a period of 3 months with bid administrations induces significant changes in skin thickness and skin elasticity as well as visual changes evaluated by the users. We have recently published a study showing the abovementioned effects (1).
The essential prerequisite for obtaining clinical effect following topical administration with RP is that the formulation is in an active form, meaning that the skin penetration is satisfactory (2,3). Only in this way can the necessary transformation of the ester (RP) into retinoic acid (RA) in the skin take place and the biological effect of RA be exerted.
By using the active RP, a pro-drug principle is utilized applying a biological inactive substance which in turn is metabolized to the active form in the skin. Treatment with different concentrations of RA has in several well performed studies been shown to have significant effects on the aging symptoms of the skin, especially on the photoaging changes (4,5,6). However, a main problem with the use of RA can be the side-effects of the dermatitis type after prolonged use. The skin tolerability for RP, on the other side, is excellent and therefore, in the active form, well suited for daily nse as a *cosmoceutic* in the treatment of aging symptoms.
The visual and measurable effects on the skin require a treatment period of at least 3 months, using the agent twice daily. Questions have been raised if and to what extent the therapeutic effect will be reduced if treatment is stopped, or whether it is required with a life-long treatment with optimal doses, or if a maintenance dose can be used when the effect of RP once is established.
To our knowledge relatively little information have been published on the long-term effect of antiaging treatment, the possible reversibility of the symptoms following cessation of therapy, and to what degree maintenance therapy is sufficient (4,5,6).
On this background we decided to carry out a study to investigate the long-term effect of RP-treatment in a group of subjects having been treated for a period of three months.

Material and methods

The aim of the study was to investigate if and to what extent a short-time treatment (3 months) with RP had long-term effects on skin parameters such as skin thickness, skin elasticity and visual skin quality.
The present study is a long-term follow-up of our previous short-term study. The 20 female subjects taking part in the short-term study were invited to participate.
After concluding the comparative double-blind study using either conjugated (Formulation A) or none-conjugated (Formulation B) RP on the volar part of the forearms for a period of three months, none of the subjects had used topical and/or systemic treatment for aging symptoms.
After a therapy-free period of exactly 12 months, the participants were invited to remeasurements of skin thickness and skin elasticity with the same method as used in the short-term study. The instrument used are the DERMASCAN A and the DERMAFLEX (Cortex Ltd., Århus; Denmark), which in several well-performed studies have been validated to give reliable results for these two parameters (7). In addition the subjects were asked to jugde the difference in visual skin quality (smoothness and glow), between the two previously treated forearms by giving preference to the arm they thought had the best skin quality. The choices were right or left arm respectively or no difference between the arms.
A separate study to objectify and check the blindness of the initial double-blind study was also carried out. Each of the earlier treated women were asked once again to test the two different formulations; the conjugated (Formulation A) and the unconjugated (Formulation B) form of RP, and were asked to rate the ointments accor-

ding to the cosmetic properties. The answering alternatives were preference for formulation A or B or no difference between the formulations.

Results

Study population

All the 20 female subjects participating in the short-term study responded positively and took part in the follow-up study. The mean age was 51.3 years (SD 6.4).

Efficacy parameters, skin thickness and elasticity

All skin parameters were measured by the same person (ET), who also performed the measurements in the short-term study. Measurments were performed at the mid-region of the volar part of the forearms. All measurments were done in triplicate and the average values were used for statistical evalution.

The results from the DERMASCAN and the DERMAFLEX measurements are shown in Tables I and II, respectively.

As can be seen from Table I, the skin thickness is reduced from the average value of 1.19 mm after therapy to 0.98 mm after 12 months of no treatment. During the short-time study the skin thickness on the arm treated with the active ointment increased from the average value of 0.91 mm to 1.19 mm, e.g. an increase of about 31%. During the therapy-free period the skin thickness is reduced to an average value of 0.98 mm meaning that about 75% of the therapy effect is lost. By other words about 25% of the original therapy effect as regards skin thickness is still present after a therapy-free period of one year.

Comparing the arms treated with conugated (A) and the none-conjugated (B) ointments the difference in skin thickness is 0.09 mm after one year, which is a significant difference ($p < 0.05$).

As can be seen from Table II, the skin elasticity is reduced from the average value of 71.5% after therapy to 63.0% after 12 months of no treatment. During the short-time study the skin elasticity on the arm treated with the active ointment increased from the average value of 60.4% to 71.5%, e.g. an increase of about 18%. In the therapy-free period the skin elasticity is reduced to 63.0%, meaning that 76.6% of the therapy effect as regards skin elasticity is lost. By other words about 23.4% of the original therapy effect is still present after a therapy-free

Table I

Changes in skin thickness (mm) during a 12 month period after cessation of therapy with RP ointments compared with values at the end of a 3 month treatment period.

Arm treated with formulation		End of short-term study	After 12 months
A*	Mean (SD) Range	1.19 (0.10) 0.87 - 1.32	0.98 (0.09) 0.75 - 1.25
B	Mean (SD) Range	0.93 (0.10) 0.74 - 1.10	0.89 (0.10) 0.71 - 1.10

Table II

Changes in skin elasticity (%) during a 12 month period after cessation of therapy with RP ointments compared with values at the end of a 3 month treatment period.

Arm treated with formulation		End of short-term study	After 12 months
A*	Mean (SD) Range	71.5 (7.9) 50.9 - 84.2	63.0 (7.3) 45.9 - 80.2
B	Mean (SD) Range	60.2 (6.5) 44.7 - 70.4	59.2 (7.0) 44.0 - 70.1

period of one year. Comparing the arms treated with conjugated (A) and none-conjugated (B) ointments the difference in skin elasticity is 3.8% after one year which is statistically significant ($p < 0.05$).

Discussion

The result from the present study shows that some of the significant changes obtained by a 3 month treatment with an active (conjugated) RP ointment, in skin thickness, skin elasticity and visual skin quality are still detectable one year after cessation of therapy. Approximately 25% of the original effect in the objective parameters following treatment with active RP is still present after one year.

To our knowledge no clear-cut recommendations have been given how long-term antiaging therapy with topical agents, that either be RA or RP, should be given. In one study no change in skin parameters could be detected after a one month cessation of treatment with RA (4), while in another study a maitenance treatment with administration of RA 3 to 4 times a week (6), as compared to daily administrations during the active treatment phase, is recommended. The data backing these recommendations are, however, limited. For the long-term use of RP we have not been able fo find dose recommendations at all. The data from our study do, however, indicate that the effect of RP-treatment will vanish if the treatment is stopped even if a not negligible part of the effect is still present after a treatment-free period of 12 months.

Several factors have taken into consideration when recommending maintenance treatment with RP for aging symptoms of the skin. At present we have no knowledge of how long time treatment should be given before maximum effect is established. From the literature it seems that treatment periods of 8-12 months, or even longer, with RA will be neccessary in order to obtain maximum effect. A similar (or longer) treatment will probably also be needed for RP.

After obtaining the effect of RP during a three months treatments, we anticipate from these data that further studies sould be performed showing the optimum treatment time for reaching the maximum effect on skin thickness and elasticity. We suggest already now that an application once daily may be sufficient to maintain the results of the earlier reached effect of RP.

Visual difference in skin quality.

The subjects preference for skin quality on the arms are listed in Table III, and are related to

Table III

Subject preference (N=20).

	Arm treated with		No difference
	A*	B	
Best skin quality	11	3	6

Table IV

The distribution of subjects giving preference to the two ointments (N=20).

	No. of subjects
A*	8
B	7
No difference	5

the treatment schemes. The subjects were giving preference without knowing the treatment randomization in the short-term study.

As can be seen from the table, it is a significant preference for the arm that had been treated with the active RP-ointment during the short-term study ($p < 0.05$).

Objectifyng the blindness of initial study

In order to test if the blinduess of the original study was really valid, the participants were asked to judge the ointments from a cosmetic point of view. The results are presented in Table IV. As can be seen from the Table IV, no difference in preference was detectable and thns it was probably not possible to identify the active form of the ointment during the double-blind part of the study.

* *Trade Name: Sincera ®, Medicina AB, Lund.*

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HIPOALLERGIC COSMETIC EMULSION WITH AZELAIC ACID FOR PROPHYLAXY AND TREATMENT OF ACNE VULGARIS

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Synopsis

Acne vulgaris with its many clinical forms is the commonest skin disease among young people, which is very resistant and dysmorphophobic and represents a big problem for the patients as well as for their physicians doctors. The authors produced an hypoallergenic cosmetic emulsion on the base of natural ingredients, without special preservatives: apple pectin as emulgator, sunflower oil and 10% and 20% Azelaic acid. These two different concentrations for two purposes: prophylaxis and therapy. The clinical results from its application in a 100 of patients with different forms of Acne, show a general favorable effect: (90%), 54% very good and 36% good. The distribution of the positive influence in the different forms of Acne is as follows: 100% in *Acne comedonica*; 65% in *Acne papulo-postulosa* and 36% in *Acne nodulo-cystica*. The tolerability of the emulsion is perfect. The hypoallergic emulsion with Azelaic acid is a new original effective and well tolerated cosmetic product for prophylaxis and treatment of Acne vulgaris, especially for sensitive patients and comedonic and papulo-pustular forms.

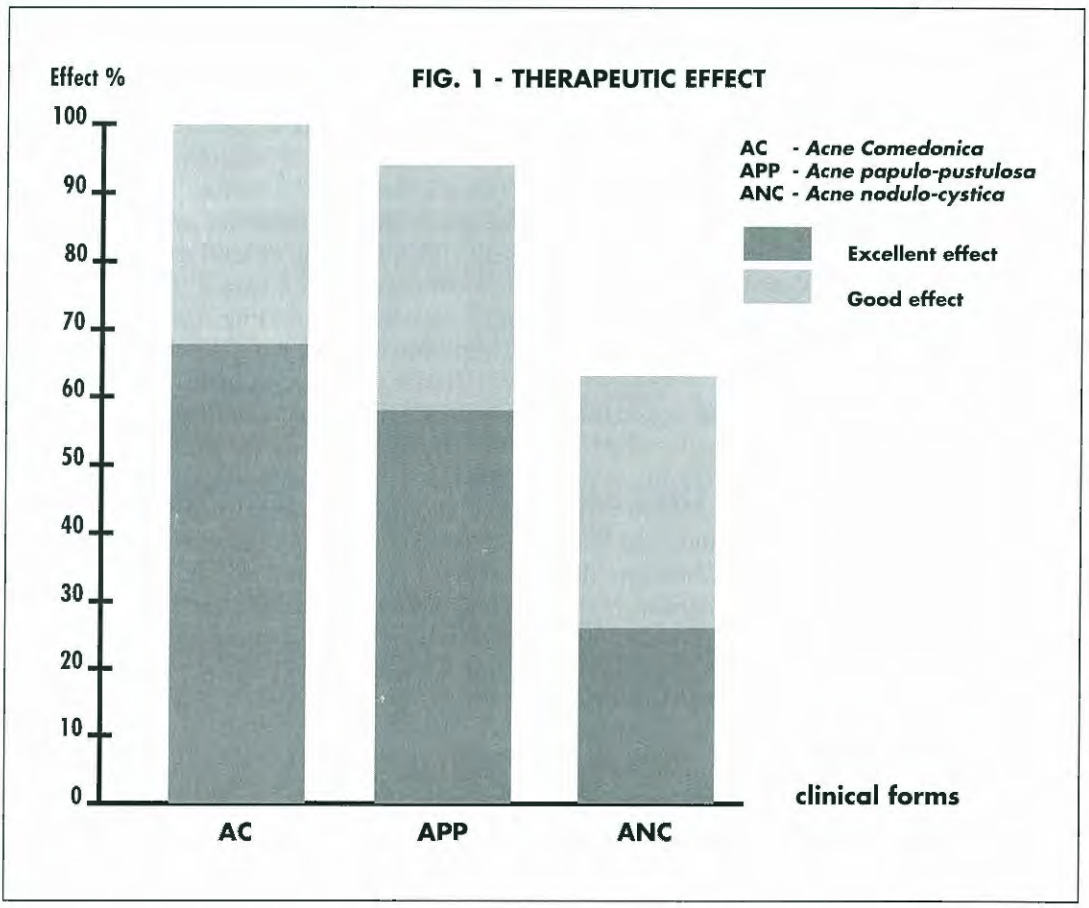
Riassunto

L'acne volgare con i suoi molteplici aspetti clinici rappresenta la più comune patologia che affligge i giovani. Per la sua resistenza alle diverse terapie ed al suo lungo decorso rappresenta un grande problema sia per i pazienti che per la classe medica. Gli autori hanno sperimentato una emulsione cosmetica ipoallergenica formulata su base vegetale. Come emulsionante è stata utilizzata la pectina delle mele, come fase oleosa l'olio di girasole e come principio attivo l'acido azelaico a due diverse concentrazioni: al 10% per la profilassi dell'acne ed al 20% per la terapia vera e propria. I risultati clinici ottenuti su 100 pazienti affetti da diverse forme di acne hanno mostrato un'effetto favorevole per il 90% suddiviso in 54% molto buono e 36% buono. La distribuzione dell'influenza positiva nelle diverse forme di acne è stata: 100% nell'acne comedonica, 65% nell'acne papulo-pustolosa e 36% nell'acne nodulo-cistica. La tollerabilità dell'emulsione si è rivelata perfetta. L'emulsione ipoallergenica con acido azelaico rappresenta un nuovo ed originale presidio cosmetico ben tollerato ed utilizzabile per la profilassi ed il trattamento sia nelle forme di acne volgare, che di pazienti con cute sensibilizzatata affetti da acne comedogenica e papulo-pustolosa.

Table I.

Clinical effect of AA-Emulsion by different forms Acne

CLINICAL FORM	EFFECT			
	very good	good	without	all
Acne comedonica	23	12	0	35
Acne papulo-pustulosa	26	17	3	46
Acne nodulo-cystica	5	7	7	19
All	54	36	10	100



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I. Pharmacist's legal responsibility originates from law, regulations and administrative action laid down by public authorities and governing the specific areas he deals with as a retailer. At the same time he is subjected to the Penal Law and can be prosecuted by the Pharmacist Board if his behaviour is in violation to the professional code which he is bound to. In any event the pharmacist as a retailer is liable for every damage caused to a customer and may be required to compensate the injured party.

The possibilities of legal claim against the pharmacist seem to be increased as one moves from medicine to goods other than drugs, since the relationship between buyer and seller is no longer "protected" by stringent and detailed regulations, like those imposed on importers, producers, prescribers and dispensers of medicaments.

Italian law on cosmetics provides that products are not allowed to be put on the market if injury to the consumer's health can result from their use in normal conditions (1) Nevertheless any responsibility of the retailer is ruled out if cosmetics are distributed to the general public in their original pack, there is no evidence of alteration of the outer wrapping and the irregularity of the product is ascribed to inherent elements such as formulation, nature and condition of the container, use of prohibited chemicals, providing that the pharmacist, has no previous knowledge of them (2).

The last provision implies that the pharmacist has no way of preventing a faulty cosmetic from being put on the market other than by examination of its outer package for evident signs of degradation while other information will not be disclosed to him.

The legal responsibilities of the pharmacist are thus placed between these two provisions and can be ascertained on the ground of breach of contract, which departure from duty of care and strict liability might be added to, more than specific regulations issued by public authorities.

When a buyer receives from a pharmacist, or a non professional store clerk, a cosmetic product in exchange for money he (or she) enters into a contract which is regulated by the existing rules of the Common Law.

It is rather speculative to attempt to define in detail how far contractual liability is exteuded by the pharmacist's behaviour, for most of the many factors concern warranties which automatically appear as part of the sale transaction.

There is no doubt indeed that fitness for a cosmetic purpose and quality of the product itself are implied warranties which are quite common in pharmacy practice, as when a customer describes his conditions and ask the pharmacist to recommend a cosmetic treatment that will alleviate them. Similarly a pharmacist supplying a cosmetic different from that described or presented as a model by the consumer, might be liable for breach of contract.

The ability of a given cosmetic to perform is not affected by personal opinions expressed by the seller because it is assumed that the consumer is able in turn to exercise his own judgment, providing that both parties are deemed to have no special knowledge about the matter. This last requirement does not seem to be satisfied in all circumstances, because the situation differs between a pharmacist and a non professional clerk of the same store, and a product purchased at the supermarket or any other outlet where the pharmacist's intervention is excluded.

2. It must be assumed that the buyer is relying on the pharmacist's skill and judgment in selecting a particular cosmetic while an implied warranty only for average quality is expected from a pharmacist's aid. A different responsibility might, however, be proposed if special knowledge in the cosmetic area is attributed to a pharmacist by the general public.

In fact academic education provides that a student of pharmacy can take official subjects in cosmetology and one of the five specific areas suggested by the new curriculum of study (3) is referred to cosmetic products. Furthermore, po-

stgraduates studies allow a pharmacist to complete his academic formation in this particular field by enroling in one of the specialized schools of cosmetic activated by universities.
Epidemicologic data referring to the frequency of cosmetic damage in relation to the quality of the consultant give further support to the difference in specific knowledge existing between the pharmacist and non professional clerks (4).
Thus the attitude of the consumer is in line with both the university training and the general practice of the pharmacists so that professional liability can be contemplated in addition to contractual liability common to every retailer.
Legal responsibilities for consulting have been given considerable attention recently and the risk of future litigation is reducing the acceptance of the new wider role that most community pharmacist expect or pretend to have.
There is little doubt that a pharmacist owes a duty of care to patients to whom he gives advice when dispensing a medicament. If damage results from wrong warnings or lack of necessary advice he might well be liable for breach of contract. On the other haud, it is still questionable if the same principle applies to industrial cosmetics dispensed in a pharmacy and whether breach of duty of care can be ascribed to a pharmacist. Nevertheless consulting is to be taken into account in retailing cosmetics particularly when the manufacturer has failed to caution adequately, or at all, the consumer through the presentation of the product.
The extent to which a pharmacist can be liable for negligence, either contractual or professional, is not easy to decide, because the national law on cosmetics and consequently administrative regulations do not consider mandatory either inserting leaflets or sealing the outer packaging of a cosmetic product.
At the moment warnings and precautions are supposed to be displayed on the label only if a cosmetic contains one or more chemicals for which specific conditions of use are imposed (5). At the same time, indication of qualitative and quantitative composition of a cosmetic is not a labelling requirement. Future legislation, following EC directive (6) will require qualitative composition.
Nevertheless the consumer's interest being paramount, a buyer must receive advice and information on the use of cosmetics so that the desired results can be attained. He must also be warned against potential damage and given adequate precautions.
The pharmacist need not be concerned with all foreseeble risks which are remote for the consumer. It is up to this professional to decide how much of information should be disclosed and to verify whether a particular danger is possible, having in mind the medication history of the buyer. The pharmacist is the only cosmetic retailer who can have access to the medication records of a consumer without violation of his privacy and confidentiality.
This takes us back to the duty of care owed by a pharmacist which is added to the contractual liability common to all retailers, and which is the expression of the different professional condition.
3. Under the civil law someone who has suffered damage from a product can obtain compensation only if he can prove that the manufacturer or the retailer are at fault or involved in the alleged complaints. Liability without proof of negligence is rarely established even if it is clear from evidence that serious injuries may occur even in the absence of negligence.
Under Council directive 85/374/EEC relating to strict liability from defective products, a claimant no longer needs to prove a producer's negligence and the manufacturer is assumed to have known the damage which can be caused by the use of his product (7).
Strict liability doctrine is applied to all products; therefore a pharmacist is liable for medicines and other goods as cosmetics which the consumer gains access to through a sale transaction.
Strict liability did not change the existing penal law. It only made it easier for an injured person

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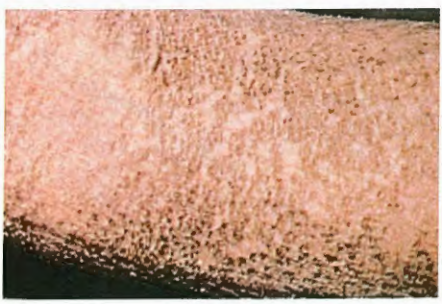
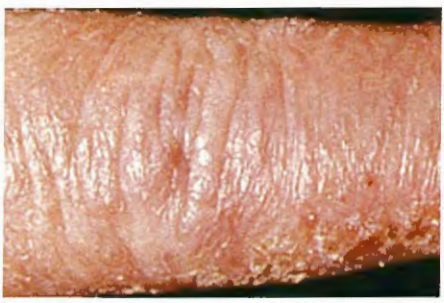


Ipercheratosi intrinseca



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