



USE OF iS CLINICAL® PRODUCTS DURING PREGNANCY AND NURSING

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iS CLINICAL by INNOVATIVE SKINCARE products are safe to use during pregnancy and nursing (lactation). Our products are classed as cosmetic by the United States Food and Drug Administration (FDA) and, as such, are non-systemic. This means they do not penetrate through the skin, into the blood stream, and to other organs such as the uterus or breast. Therefore all iS CLINICAL products should be safe to apply to skin during pregnancy and nursing.

Cosmetic products are not designed for oral ingestion. Consequently, when the mother is nursing, these products should not be placed directly on nipples in order to avoid ingestion by the infant.

INNOVATIVE SKINCARE recommends that the mother or mother-to-be also consult with her obstetrician, pediatrician, or other health care provider and follow the recommendations of the provider.

These company recommendations apply to our products only and are not intended to be comments about any other cosmetic brands. In particular, these recommendations do not apply to topical products that are known to be systemically absorbed into the blood stream and thereby delivered to other organs. Hydroquinone is an example of a topical product that is delivered systemically and can harm the developing fetus.

VITAMIN A (RETINOL)

Some of our company's topical products do contain vitamin A (retinol) or retinyl esters such as retinyl palmitate. These products are also deemed safe during pregnancy and nursing by the US FDA for the same reason, i.e. they are not systemically absorbed. Research

studies support the FDA's position that topical vitamin A is safe during pregnancy because it is not absorbed into the bloodstream. It is known that increased systemic levels of vitamin A related to taking oral supplements can be teratogenic, i.e. cause fetal malformations. Ingesting vitamin A or the retinyl esters such as retinyl palmitate can lead to measurable blood levels of vitamin A, therefore taking oral supplements of vitamin A during pregnancy is not recommended. Obstetricians are aware that oral vitamin A can be teratogenic and usually recommend against taking any additional oral vitamin A during pregnancy. Some obstetricians are so cautious as to also extend their recommendation to the topical forms of vitamin A even though they have been proven to be non-toxic during pregnancy. Again, our company recommends that the consumer follow the recommendations of their individual health care provider.

The FDA position regarding safety of topical vitamin A applies to both topical vitamin A and topical retinyl esters only such as retinyl palmitate. It is important to clarify that the chemical derivatives of vitamin A which are classed as drugs, including tretinoin (RetinA) and isotretinoin (Accutane) are not made by our company, are not topical cosmetics, are classed as medications (drugs), and are different types of compounds not included in these comments. The user should consult US FDA and US DEA (Drug Enforcement Administration) recommendations specifically for these substances. In particular, isotretinoin is known to be teratogenic and should not be used if the user is pregnant or may become pregnant during use of the medication. Physicians managing patients on isotretinoin (Accutane) are very careful to assure that the female patient not be pregnant or become pregnant while taking this medication.



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