

## ClerVitaRx® Acne Cream

0.05 % Tretinoin

### Patient and Healthcare Professional Information

#### Please read this entire leaflet before using this medication.

If you require any further information, please ask your doctor or pharmacist. This medication has been prescribed specifically for you. Do not give this medication to anyone else as it may not be appropriate for him/her even if he/she shows the same symptoms as you do. Keep this leaflet as you may need to read it again.

**Medicine Classification:** Prescription medicine

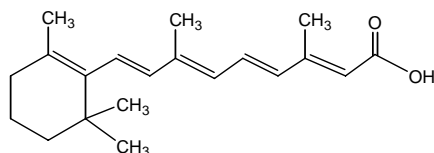
**Composition** 0.05% Tretinoin in a water soluble cream base

**Pharmacotherapeutic class:** Topical retinoid

#### What is ClerVitaRx® Cream and when should it be used?

ClerVitaRx® contains tretinoin which is used for the treatment of acne vulgaris, primary grades I-III. Tretinoin is a derivative of Vitamin A and is the treatment of choice for comedonal acne, or whiteheads and blackheads (pimples). Tretinoin is also the only topical medication that has been proven to improve wrinkles.

**Chemical Name and Structure** Chemically, tretinoin is all- *trans* -retinoic acid, also known as (all- *E*)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid. It is a member of the retinoid family of compounds and tissue active metabolite of naturally occurring Vitamin A. It has therefore been designated 'partial Vitamin A'. Tretinoin has a molecular weight of 300.44. Tretinoin has the following structure:



**How do I use this medication?** Unless otherwise directed by your doctor, apply ClerVitaRx® Cream very lightly to your skin once a day, at bedtime, to the area where acne lesions (pimples) appear, using enough to cover the entire affected area. A small amount goes a long way. In the morning wash your face with a mild facial scrub or rough wash cloth. This will help reduce the noticeable flaking. After washing, apply a good water-based moisturizer. The moisturizer will make the drying effect of the medicine more tolerable. If flaking occurs during the day use a wash cloth to remove it and apply more moisturizer, or just apply moisturizer. When you first start using ClerVitaRx®, apply it every other night or every 3rd night. The flaking and irritation side effects are usually the worst in the first 2 weeks of application. As your skin adjusts to the medicine, you can apply it more frequently. If you notice an increase in the irritation or flaking, it's ok to take a break for a couple of days. Just don't stop completely without consulting your doctor.

**How does it work?** The exact mechanism is unknown but it is recognized that tretinoin reduces the production and stickiness of blackheads to the hair follicle. It encourages collagen production, and inhibits melanin production, and there is minimal absorption through the skin.

**How well does it work?** It works slowly to prevent new pimples and will also have an anti-inflammatory effect. Signs of improvement may be noticed after two to three weeks, but more than six weeks of therapy is required before definite beneficial effects are seen. Once the acne lesions have responded satisfactorily, it may be possible to maintain the improvement with less frequent applications. Benefits in repairing the effects of sun damage, including wrinkles, are much slower and can often take six to twelve months. You may notice a reduction of fine lines and blotchy pigmentation.

**Why should I not use this medication?** ClerVitaRx® should not be used by anyone allergic to any of the ingredients. Use of the product should be discontinued if hypersensitivity to any of the ingredients is noted. This cream is not recommended as mono-therapy in cases of severe pustular and deep cystic nodular varieties of acne (acne conglobata).

**Will There Be Adverse Effects?** Topical use may induce severe local inflammation and peeling at the site of application resulting in dry, red, scaly skin. The skin of certain sensitive individuals may become excessively red, blistered, or crusted. Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with utmost caution in patients with eczema. During the early weeks of therapy, an apparent increase in inflammatory acne lesions may occur. This is due to the action of the medication in deep, previously unseen lesions and should not be considered a reason to discontinue therapy. Inflammation of the skin can result in a short term increase or decrease in pigmentation. True contact allergy to topical tretinoin is rarely encountered. Some individuals have been reported to have heightened susceptibility to sunlight while under treatment with tretinoin. The effect of increased skin cell turnover can be irritation and flaking. For this reason, many people stop using tretinoin after a couple of days to weeks, then think that it didn't work. It is important to realize that ClerVitaRx® cream is very effective for whiteheads and blackheads, but it may take 6-9 weeks to see a noticeable difference. It takes at least 6 months to see a noticeable difference in wrinkles. The best benefit is seen if ClerVitaRx® is used for at least a year. If the degree of local irritation is severe, your doctor may advise you to use the medication less frequently, discontinue use temporarily, or discontinue use altogether. All adverse effects of tretinoin are reversible when therapy is discontinued.

#### Can I use this medication when pregnant or breastfeeding?

Reproduction studies performed in rats and rabbits at dermal doses up to 50 times the human dose (assuming the human dose to be 1000 mg of cream per day) have revealed no evidence of impaired fertility or harm to the foetus due to tretinoin. However, there are no adequate and well-controlled studies in pregnant women and so this drug should not be used by pregnant women or those planning to become pregnant during treatment. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ClerVitaRx® is used by a nursing mother.

**Overdosage:** ClerVitaRx® is indicated for topical use only. If used excessively, no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of vitamin A.

**Storage Conditions:** All ClerVitaRx® topical preparations should be stored below 30°C

**Package Quantities:** Cream 0.05%, 20g

**Manufactured By:** LaGray Chemical Company Ltd., Nsawam, Ghana

**Manufactured for:** LaGray Chemical Company, Inc., Chicago, Illinois, United States of America



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