RETIRIDES - Information for the user and usage instructions

Translated from Spanish by Vaughter Wellness Ltd.

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1. Name of the product

RETIRIDES 0.025% cream 30 g.
RETIRIDES 0.05% cream 30 g.
RETIRIDES 0.1% cream 30 g.

2. Qualitative and quantitative composition

One gram of RETIRIDES 0.025% cream contains 0.25 mg tretinoin and excipient QS 1 g.
One gram of RETIRIDES 0.05% cream contains 0.5 mg tretinoin and excipient QS 1 g (0.5%).
One gram of RETIRIDES 0.1% cream contains 1 mg tretinoin and excipients QS 1 g (0.1%).

3. Pharmaceutical form

Emollient cream.

4. Clinical Particulars

4.1 Therapeutic indications

Acne:

Topical treatment for acne (also called acne vulgaris), particularly with comedones (blackheads and whiteheads), pustules and papules.

Photoageing:

RETIRIDES 0.05% CREAM

Topical adjuvant treatment for the reduction of fine lines, mottled hyperpigmentation and roughness of facial skin caused by secondary photoageing of the skin from chronic sun exposure in patients who are unable to reduce these effects through careful skin care and protecting their skin from the sun only.

RETIRIDES 0.05% CREAM is not a cosmetic and should only be used by prescription and as part of an intensive skin care programme including teaching patients to avoid the sun

and the use of sun protection and moisturising products.

RETIRIDES has not been proven to have a therapeutic effect on the most severe signs of solar exposure such as deep wrinkles, yellowish tint, lentigines (dark spots), talangiectasias (dilated blood vessels), loss of skin elasticity, keratinocytic and melanocytic atypia or dermal elastosis.

4.2 Posology and method of administration

Acne treatment: Depending on skin type and severity of the condition, the cream with the appropriate concentration (RETIRIDES comes in concentrations of 0.025%, 0.05% and 0.1%) is prescribed together with the number of daily applications. It is recommended that treatment should begin with a lower concentration cream applied once a day. Depending on the patient's response to treatment, the concentration and/or number of applications may be increased.

Correct application of the product as an acne treatment: Individuals undergoing treatment should avoid washing their face too often, not more than twice or three times a day, and should use a neutral soap and dry without rubbing. The cream should not be applied until half an hour after the face is washed.

Photoageing: RETIRIDES 0.05% CREAM should be applied sparingly only once a night, lightly covering the affected areas (face or arms). RETIRIDES 0.05% CREAM may produce temporary itching and a sensation of heat. When RETIRIDES 0.05% CREAM is applied, there is normally a slight temporary redness similar to light sunburn. Applying RETIRIDES 0.05% CREAM more often or in larger amounts will not lead to faster or improved treatment. It may cause your skin to become very irritated, with effects such as redness, itching and peeling, among others, (see Special warnings and precautions for use). All areas to be treated with RETIRIDES 0.05% CREAM must be clean. Use of a mild, non-medicinal soap is recommended.

The skin should be dried by patting and without rubbing. The skin should be left to dry for at least 20-30 minutes before RETIRIDES 0.05% CREAM is applied. Washing the treated area twice a day is enough. Length of treatment: RETIRIDES 0.05% CREAM does not bring immediate improvement to signs of photoageing. This occurs gradually during the course of treatment. Clinical tests show that the appearance of visible improvements may vary. However, definite beneficial effects are generally observed within 3-4 months of starting the treatment. The safety and effectiveness of daily

tretinoin 0.5% use have not been established for a period exceeding 48 weeks. Once the maximum beneficial effects of using RETIRIDES 0.05% CREAM have been achieved, they can be maintained by applying the cream between once and three times a week. If there is no maintenance of the therapy, the beneficial effects achieved will diminish over time. RETIRIDES 0.05% CREAM can be used with cosmetics and moisturisers during treatment. The skin should be completely clean before RETIRIDES 0.05% CREAM is applied (see Special warnings and precautions for use). Patients should be informed of the importance of protecting their skin from the sun with sun screens, moisturising products and suitable clothes. In the specific case of treatment for photoageing, the safety and effectiveness of the daily use of RETIRIDES 0.05% CREAM for more than 48 weeks have not been established either for prevention or treatment of actinic keratosis or cutaneous neoplasms.

Use in children: The safety and effectiveness of using RETIRIDES 0.05% CREAM with children has not been established.

Use by persons aged 50+: The safety and effectiveness of using RETIRIDES 0.05% CREAM with persons aged 50 years and over has not been established.

4.3 Contraindications

Background of sensitivity/hypersensitivity reactions to any of the ingredients.
Pregnancy, family or personal history of cutaneous epithelioma.

4.4 Special warnings and precautions for use

Local irritation in Acne treatment: Where acne treatment is concerned, this irritation is directly linked to the effectiveness of the product and disappears when the applications are more spread out. During the first weeks of treatment an apparent exacerbation of the condition is observed. This is a normal reaction. It is caused by the rapid elimination of microcysts being formed in the deeper layers of the skin.

Photoageing: It is recommended that the treatment with RETIRIDES 0.05% CREAM should not be started or resumed while there is skin irritation (for example redness, flaking, itching and sunburn). If the degree of local irritation persists, patients should be advised to apply the cream less frequently or to stop the treatment temporarily. The use of RETIRIDES 0.05% CREAM by some individuals (for example patients with eczema,

sunburn, etc.) could cause severe local redness, swelling, itching, feeling of burning, stinging, blisters, scabs and/or flaking in the area where the cream is applied. Tretinoin has been reported to cause serious irritation in skin suffering from eczema and should be used with the greatest precaution by patients with this condition.

Patients suffering from persistent or severe irritation should discontinue treatment with RETIRIDES 0.05% CREAM and see their doctor if necessary (see Posology and method of administration).

For both acne and photoageing treatments, care should be taken with the use of other local irritant treatments, particularly those with an abrasive, drying or peeling effect (see Interaction with other medicinal products and other forms of interaction).

Extreme climatic conditions such as cold wind and low humidity may also irritate skin treated with RETIRIDES 0.05% CREAM and may increase dryness (see Exposure to sunlight).

Exposure to sunlight: Exposure to sunlight, including ultraviolet sunlamps (UVB) should be avoided or reduced during tretinoin use. Patients with sunburn should be advised not to use the product until they are fully recovered owing to the potentially severe irritation that could be produced on sensitive skin. Patients experiencing considerable occupational sun exposure and/or persons inherently sensitive to sunlight should take special precautions. When exposure to the sun cannot be avoided, the use of products with sun screens and protective clothing is recommended for the treated areas.

General precautions for use: RETIRIDES 0.05% CREAM must be used under medical supervision, as part of a comprehensive skin care programme, including teaching patients about the benefits of avoiding sun exposure and general skin care by using sun screens, moisturisers and protective clothing. Care should be taken to avoid contact with the eyes, eyelids, corners of the nose, mouth, mucus membranes and other areas where this treatment is not indicated in order to minimise further skin irritation. Care should be taken not to allow build up of cream to occur in skin folds. In areas of more sensitive skin, such as the neck and forearm, there is a greater risk of irritation. It is therefore recommended that the frequency of application should be reduced.

The effectiveness of RETIRIDES 0.05% CREAM has not been established in persons over 50 years of age or in persons with moderately or heavily pigmented skin. In the specific case of treatment for photoageing, the safety and effectiveness of the daily use of RETIRIDES 0.05% CREAM for more than 48 weeks has not been established either for

prevention or treatment of actinic keratosis or cutaneous neoplasms. All areas to be treated with RETIRIDES 0.05% CREAM must be clean. Use of a mild, non-medicinal soap is recommended. Skin should be dried by patting and without rubbing. The skin should be left to dry for at least 20-30 minutes before RETIRIDES 0.05% CREAM is applied. It is more than sufficient to wash the treated area twice a day.

4.5 Interaction with other medications and other forms of interaction

RETIRIDES 0.05% CREAM should be used with care in the presence of: Concomitant topical medicinal products; personal hygiene products with an abrasive, drying or peeling effect, including soaps, shampoos, cosmetics and astringents (particularly those containing alcohol, whitening agents or perfumes), medicinal soaps and shampoos, perm fluid, electrolysis, hair removal creams and waxes and preparations and products that can dry the skin, unless treatment is made under medical supervision. RETIRIDES 0.05% CREAM should not be applied when drugs producing light sensitivity are being taken (such as Thiazides, Tetracyclines, Fluoroquinolones, Phenothiazides and Sulphonamides) owing to the risk of increased toxicity.

4.6 Pregnancy and lactation

In clinical trials with 0.05% tretinoin in emollient cream, the human topical dose based on an adult weighing 50 kg applying a maximum volume of 500 mg of 0.05% cream was 0.005 mg/kg. In studies on the reproduction in animals, oral tretinoin is known to be teratogenic and has shown to be foetotoxic in rats when administered in doses 500 times higher than the human topical dose. In studies on reproduction in rats and rabbits, topical tretinoin used at doses 1000 times higher than the human topical dose caused minor skeletal deformities, for example irregularly curved bones and partially ossified cranial bones.

Tretinoin 0.05% should not be used by pregnant women, women wishing to become pregnant and women with high risk of becoming pregnant. Although it has not been demonstrated that tretinoin for topical use has teratogenic effects, use is not recommended for pregnant women, particularly during the first three months. It is not known if tretinoin is excreted in human breast milk. Therefore, it should only be administered to breastfeeding women where the therapeutic benefits justify possible risks.

4.7 Effects on ability to drive and use machines

RETIRIDES 0.05% CREAM is administered via the skin. Its effect on the ability to drive or use machines is unknown.

4.8 Undesirable effects

The most commonly reported local reactions during therapy are: skin dryness and flaking, stinging, itching, burning sensation, severe local redness, oedema, blisters, eschars, pruritus, and temporary hypo and hyperpigmentation. These cutaneous reactions were generally slight to moderate and generally well-tolerated. They normally occurred at the start of therapy, except for skin dryness and flaking, which persisted throughout the treatment, and generally diminished during treatment (see Local irritation). Clinical studies with tretinoin 0.05% did not show incidences of genuine allergic sensitivity to contact. Increased sensitivity to sunlight and other sources of UVB light has been observed.

4.9. Overdose

Excess application of RETIRIDES 0.05% CREAM does not improve the results of treatment and may cause marked irritation, for example redness, flaking and pruritus. RETIRIDES 0.05% CREAM taken orally may lead to similar effects to those associated with excessive vitamin A intake (for example pruritus, skin dryness, arthralgia, anorexia, and vomiting).

5. Pharmaceutical particulars

5.1 List of excipients

De-ionised water, lactic acid, cetyl alcohol, decyl oleate, isopropyl myristate, non-selfemulsifying glycerol monostearate, sodium chloride 20% concentration, acetylated lanolin alcohol, perfume vertalina 72, ceteareth-30, proline, PEG-400 monostearate, urea, collagen, sodium citrate, methylparaben, propylparaben, vitamin E.

5.2 Incompatibilities with other medications

None.

5.3 Shelf life

3 years.

5.4 Special precautions for storage

No special storage conditions are required. Close the container well after use.

5.5 Nature and contents of container

Aluminium tubes covered in a latex band and enamelled with modified polyester resins. The caps are made from polypropylene. The container holds 30 g of product.

5.6 Instructions for use/handling

None stated.

5.7 Producer

LABORATORIOS OTC IBÉRICA S.A. C/Monturiol, 2 Pol. Ind. Sur - 08754 EL Papiol (Barcelona).