

Use of KGF in the treatment of menopausal disorders.

KEYWORDS

- ☐ MENOPAUSE
- ☐ VAGINAL ATROPHY
- ☐ ESTROGENS
- ☐ KGF
- ☐ THERAPY

AREA

- ☐ PHARMACEUTICAL

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Patent Type

Patent for invention.

Ownership

Sapienza University of Rome 100%.

Inventors

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Industrial & Commercial Reference

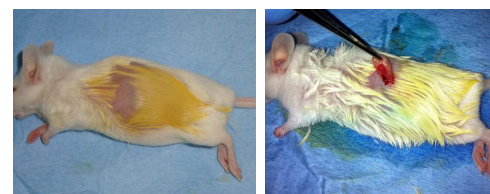
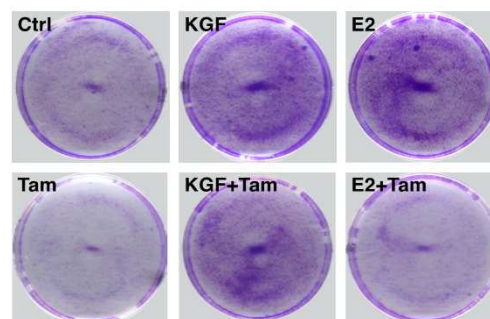
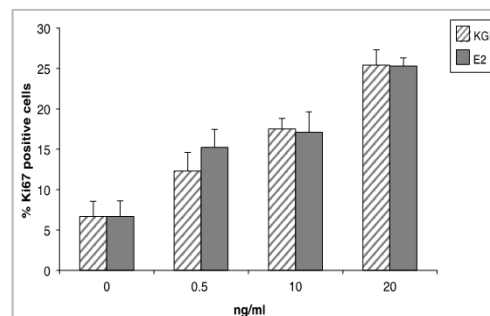
The present invention is referred to the medical/pharmaceutical field.
In particular, it is directed to the business of menopausal products.

Time to Market

The preferential pharmacological composition has been tested in vitro on vaginal mucosal cells and in vivo on murine model.

Availability

Cession, Licensing, Research,
Development, Experimentation and
Collaboration.



Group	Estradiol (pg/ml)	KGF (pg/ml)
CTR	123,6±17,6	ND
OV	ND	ND
KGF low	ND	ND
KGF high	ND	ND
E2 low	20,3±0,6	ND
E2 high	202,7±9,1	ND

Abstract

The present invention relates to the medical field, in particular it refers to the use of Keratinocyte Growth Factor (KGF / FGF7) and its related pharmaceutical compositions in the treatment of vaginal atrophy, dysuria, vaginal pain and / or vaginal dryness conditions, induced by a post-menopausal state, by a surgery, by a pathology and / or by chemo / radiotherapy treatments.

Vaginal atrophy, caused by the decline of circulating estrogens, is generally treated with hormonal therapy. However, estrogens can reach the bloodstream even when locally administered, thus increasing the oncological risk. KGF, a known mitogen for epithelial cells, acts on human vaginal mucosa cells through a crosstalk with the estrogen pathways. Topical treatment with KGF is able to restore vaginal trophism in vivo, similarly to estrogenic preparations, without systemic effects since it does not pass into the bloodstream.

Publications

- ❖ Ceccarelli S, D'Amici S, Vescarelli E, et al. Topical KGF treatment as a therapeutic strategy for vaginal atrophy in a model of ovariectomized mice. J Cell Mol Med. 2014 Sep;18(9):1895-907. doi: 10.1111/jcmm.12334.



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Use of KGF in the treatment of menopausal disorders.

Technical Description

The present invention is based on the role of Keratinocyte Growth Factor (KGF) in the treatment of vaginal atrophy. It was investigated the in vitro efficacy of KGF in inducing vaginal cells proliferation and in activating specific intracellular signaling pathways.

In vivo, it was assessed the efficacy of local treatment with KGF in restoring vaginal mucosal trophism in ovariectomized mice. Studies have shown that KGF can be used as an alternative therapy for post-menopausal vaginal atrophy or for other dysfunctions such as dysuria, vaginal pain and / or vaginal dryness, as it is able to restore both mucosal trophism (epithelium thickness and proliferative ability of the basal layer) and its lubrication (presence of muciparous cells).

Technology & Advantages

The different compositions of the invention can be prepared by mixing KGF with physiologically acceptable carriers, excipients or stabilizers. The topical release of KGF is targeted for the local treatment of menopausal disorders, and therefore it is suitable to counteract symptoms such as dryness and vaginal atrophy.

The advantages of using KGF instead of estrogens are due to its proteic character, which determines the lack of transition through the epithelial barrier. In fact, the physiological expression of its specific receptor on cell membrane allows KGF to perform its function locally, without entering the systemic circulation. Therefore, KGF topical treatment shows no systemic side effects.

Applications

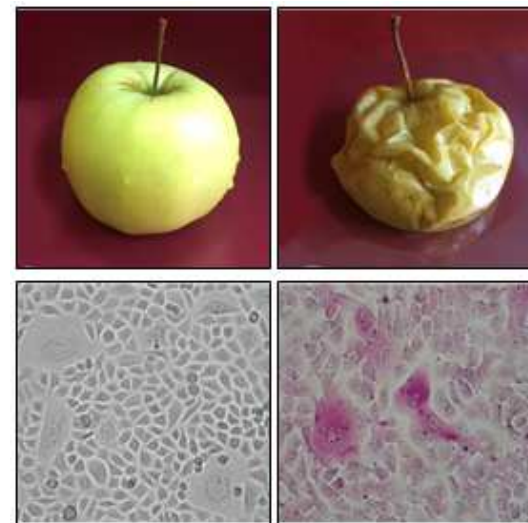
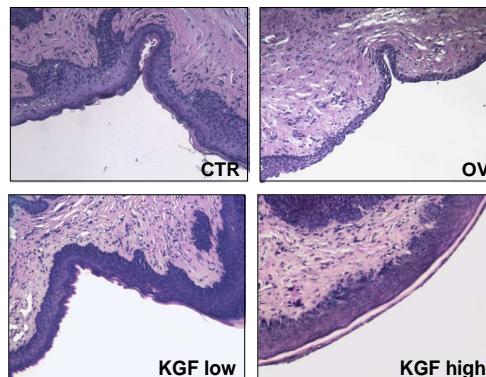
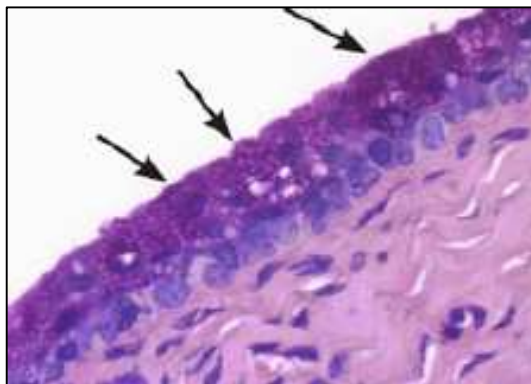
The invention concerns pharmacological preparations containing Keratinocyte Growth Factor (KGF / FGF7), for use in the treatment of vaginal atrophy, dysuria, vaginal pain and / or vaginal dryness induced by a post-menopausal state, by a surgery, by a pathology and / or chemotherapeutic or radiotherapeutic treatments.

Topical KGF can therefore replace local therapies already in use, i.e. estrogen-based formulations.

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