

Flamigel® RT

Indications

Flamigel® RT is a hydro-active colloid gel for the symptomatic treatment of low-grade radiotherapy-induced skin reactions such as red, dry, itching, flaking, peeling or irritated skin (dry desquamation). It can also be used to treat more severe skin reactions that can develop at a later stage of radiotherapy as partial skin breakdown and appearance of oozing blisters (moist desquamation).

Flamigel® RT delays the onset and reduces the incidence of radiotherapy-induced moist desquamation.

What are radiotherapy-induced skin reactions and radiotherapy-induced moist desquamation?

Repeated doses of radiotherapy can cause side effects known as radiotherapy-induced skin reactions. The first symptoms can start as red, dry or itchy skin (dry desquamation). As the radiotherapy treatment continues, the symptoms may develop into skin breakdown and oozing blisters (moist desquamation). The symptoms in general do not stop when the radiotherapy stops, they often continue or even increase until approximately 2 weeks after the radiotherapy treatment has finished.

Intended use

Flamigel® RT hydro-active colloid formulation reduces the intensity of early symptoms of radiotherapy-induced skin reactions such as red, dry, itching, flaking, peeling or irritated skin (dry desquamation). It hydrates the affected skin area and restores moisture balance. Flamigel® RT helps to reduce pain, redness and heat by its cooling effect and, therefore, soothes the exposed skin areas. Flamigel® RT also provides a barrier against external contamination. Flamigel® RT delays the onset and reduces the incidence of radiotherapy-induced moist desquamation.

Additionally, Flamigel® RT helps to create optimal healing conditions to accelerate cell renewal, allowing the compromised skin to heal fast and so reduce the likelihood of scarring.

Applying Flamigel® RT helps to continue the prescribed radiotherapy treatment by delaying the onset and reducing the incidence of radiotherapy-induced moist desquamation.

When to use

Start using Flamigel® RT when you have red, dry, itching, flaking, peeling or irritated skin (dry desquamation) during your radiotherapy and continue to use Flamigel® RT whilst your symptoms persist and for as long as your radiotherapy centre advises you to.

As the symptoms often continue even after the radiotherapy has ended, your radiotherapy center may also advise you to continue applying Flamigel® RT for some time after your course of radiotherapy has finished.

How to use

Wash hands before and after application of Flamigel® RT. Clean and dry the treated area gently before applying Flamigel® RT.

Apply 3 times per day a liberal amount of Flamigel® RT to the affected area and a large zone around it and gently distribute.

It is important to follow the general skin care recommendations of your radiotherapy centre.

Contraindications

Do not use Flamigel® RT when there is a known allergic reaction to any of the ingredients (see Ingredients).

Special warnings and precautions for use

- For external use only.
- Do not use Flamigel® RT on the eyelids or in the eyes. If Flamigel® RT comes into contact with the eyes, rinse the eyes with running water and consult a doctor or nurse.
- In case of open wounds where the dermis is substantially breached or when moist desquamation occurs over large surfaces (large confluent moist desquamation lesions) it is recommended to apply a treatment for large or deep wounds. In case of doubt, consult your treating physician or nurse.
- On extensive weeping or infected wounds, consult a doctor before using Flamigel® RT because other complementary treatments might be necessary.

Undesirable effects

Side-effects such as irritations or allergic reactions are rare but can occur. Stop immediately using Flamigel® RT if irritation or allergy occurs.

If any serious incident occurs in relation to the device, or your condition worsens, please contact your doctor or pharmacist. This incident should be reported to Flen Health and the competent authorities of your country (the distributor, see below, can give you details of who this is). By reporting an incident, you can help provide more information on the safety and the efficacy of this medical device.

Storage conditions

- Store at room temperature (< 25°C), in a dry place and in the original packaging.
- Close the tube after use.
- Once opened, and if recapped carefully, a tube of Flamigel® RT can be stored and used for one year
- Do not use Flamigel® RT after the expiry date shown on the pack. The expiry date (USE BY: Year/Month) is the last day of the indicated month and year.

Special precautions for disposal

Any unused product or waste material should be disposed in accordance with local requirements.

Ingredients

Hydrocolloid, Arginine, Purified water, Macrogol, Branched Chain Fatty Acid (BCFA), Methyl-p-hydroxybenzoate (E218), Propyl-p-hydroxybenzoate (E216), Disodium EDTA.

How supplied

Tubes of 10g, 15g, 20g, 25g, 40g, 50g, 100g and 250g. Sachets of 4g.

Not all pack sizes may be marketed.



Manufacturer

Flen Health NV, Blauwesteenstraat 87, B-2550 Kontich, Belgium

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Medical device

