

## Safety Alert

May 2025

### Tacrolimus - risks of skin cancers and Kaposi's sarcoma

EDA performs label update to include the following:

#### **Special warnings and precautions for use:**

##### **Lymphoproliferative disorders and malignancies**

Patients treated with tacrolimus have been reported to develop Epstein-Barr Virus (EBV)-associated lymphoproliferative disorders and other malignancies, including skin cancers and Kaposi's sarcoma .

##### **Undesirable effects:**

Neoplasms benign, malignant and unspecified (incl. cysts and polyps)

Patients receiving immunosuppressive therapy are at increased risk of developing malignancies. Benign as well as malignant neoplasms including EBV-associated lymphoproliferative disorders, skin malignancies and Kaposi's sarcoma have been reported in association with tacrolimus treatment.

#### **Background:**

##### **Kaposi sarcoma**

is a type of cancer that forms in the lining of blood vessels and lymph vessels. The cancer forms growths of cells, called lesions, on the skin. The lesions often form on the face, arms and legs. The lesions may look pink, red, purple or brown

##### **Skin cancer is cancer**

starts as a growth of cells on the skin. The cells can invade and destroy healthy body tissue. Sometimes the cells break away and spread to other parts of the body.

Many kinds of skin cancer exist. The most common skin cancers are basal cell carcinoma and squamous cell carcinoma. While these are the most common, they often can be cured. The most dangerous form of skin cancer is melanoma. It is more likely to spread, making it harder to cure.

##### **Therapeutic Indication of tacrolimus:**

Prophylaxis of transplant rejection in adult kidney or liver allograft recipients. Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

##### **References:**

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