Non-interventional Study Actikerall®

Biometric Statement

Number of Patients: N = 294

Monitoring Period: October 2015 – June 2016

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Sponsor:

Summary

Summarizing the most important results presented in this Biometric Statement, the present NIS on the clinical effectiveness of Actikerall® and sequential Solaraze® treatment in patients with AK lesions under dailiy routine conditions comprised 294 patients from 41 centres in Austria. The safety population (SAF), i.e. all patients with actinic keratosis who were treated with Actikerall® and for whom Actikerall® therapy data were documented, comprised 294 patients from 41 centres (ref. chapter 3).

Female patients comprised 35.37% and male patients comprised 62.24% of the SAF. The mean age of the patients was 74.60±9.00 years. Mean height was 171.35±9.52 cm, and mean body weight was 76.70±14.21 kg (ref. chapter 6.1). The most frequent skin type according to the Fitzpatrick scale was type II (59.18% of the SAF). 26.53% of the SAF were exposed to the sun during work, and 88.10% were exposed to the sun during leisure time (ref. chapter 6.1).

The mean time since first diagnosis of actinic keratosis was 2.95±4.19 years. At the start of the stuy period, the mean total number of AK lesions was 7.13±6.18 lesions (Min: 1.0, Max: 50.0 lesions, ref. chapter 6.2).

As defined by Almirall, AK lesions on face, head/neck, arms, legs, and trunk were evaluated separately. Regarding the patients with AK lesions in the face at start of the study (i.e. N=225 patients with a total of 820 AK lesions on forehead, eyelids, nose, mouth, cheek, or chin), the mean size of the AK lesions was 5.77±4.87 mm (Min: 0.3, Max: 80.0 mm, ref. chapter 6.2). In patients with AK lesions on head or neck at start of the study (N=134 patients with a total of 400 AK lesions), the mean size of the AK lesions was 5.40±3.41 mm (Min: 1.0, Max: 30.0 mm). In patients with AK lesions on the arms at start of the study (N=36 patients with a total of 112 AK lesions), the mean size of the AK lesions was 4.32±2.31 mm (Min: 0.8, Max: 15.0 mm). In patients with AK lesions on the legs at start of the study (N=2 patients with a total of 5 AK lesions), the mean size of the AK lesions was 5.00±1.58 mm (Min: 3.0, Max: 7.0 mm). And in patients with AK lesions on the trunk at start of the study (N=1 patient with a total of 2 AK lesions), the mean size of the AK lesions was 3.50±0.71 mm (Min: 3.0, Max: 4.0 mm, ref. chapter 6.2).

Regarding previous treatment of the AK lesions included in this study, a previous treatment was reported for 70.75% of the SAF (ref. chapter 6.3).
At start of the study, the physicians were asked to document whether another (pre)malignant skin neoplasia had already been diagnosed previously (i.e. basal-cell carcinoma, squamous cell carcinoma, malignant melanoma, cutaneous lymphoma, Bowen's disease, or other (pre-)malignant skin neoplasias). In 41.16% of the SAF, another (pre-)malignant skin neoplasia had already been diagnosed (ref. chapter 6.4). Underlying diseases were reported for 49.32%, and medical treatment was reported for 47.96% of the SAF (ref. chapter 6.5).

At start of the study period, 86.73% of the SAF applied Actikerall® once a day. Regarding the the total duration of Actikerall® therapy, most of the SAF (51.36%) were treated with Actikerall® for more than 4 up to 6 weeks (ref. chapter 6.6).
Sequential treatment with Solaraze® was reported for 75.51% of the SAF. 72.97% of the patients with sequential Solaraze® treatment applied Solaraze® twice a day. With regards to the total duration of Solaraze® therapy, most of the patients with sequential Solaraze® treatment (70.27%) were treated with Solaraze® for ≤ 60 days (ref. chapter 6.7).

After therapy with Actikerall®, the mean total number of AK lesions was 3.79±4.75 lesions (Min: 0.0, Max: 50.0) in the SAF. In patients with sequential Solaraze® treatment, the mean total number of AK lesions was 3.92±3.65 (Min: 0.0, Max: 30.0) after therapy with Actikerall® (ref. chapter 6.9.1). In patients with AK lesions in the face at start of the study, the mean size of the AK lesions was 4.36±4.54 mm (Min: 0.0, Max: 30.0 mm) after therapy with Actikerall®. In patients with AK lesions on head or neck at start of the study, the mean size of the AK lesions was 3.70±3.19 mm (Min: 0.0, Max: 20.0 mm) after therapy with Actikerall®. In patients with AK lesions on the arms at start of the study, the mean size of the AK lesions was 2.85±1.51 mm (Min: 0.0, Max: 8.0 mm) after therapy with Actikerall®. In patients with AK lesions on the legs at start of the study, the mean size of the AK lesions was 0.50±1.00 mm (Min: 0.0, Max: 2.0 mm) after therapy with Actikerall®. And in patients with AK lesions on the trunk at start of the study, the mean size of the AK lesions was 2.50±0.71 mm (Min:
2.0, Max: 3.0 mm) after therapy with Actikerall® (ref. chapter 6.9.1).

In patients with sequential Solaraze® treatment, the mean total number of AK lesions was 1.73±2.60 (Min: 0.0, Max: 15.0) after therapy with Solaraze® (ref. chapter 6.9.2). In patients with AK lesions in the face at start of the study, the mean size of the AK lesions was 3.10±2.94 mm (Min: 0.0, Max: 15.0 mm) after sequential Solaraze® treatment. In patients with AK lesions on head or neck at start of the study, the mean size of the AK lesions was 2.70±2.74 mm (Min: 0.0, Max: 16.0 mm) after sequential Solaraze® treatment. In patients with AK lesions on the arms at start of the study, the mean size of the AK lesions was 2.31±1.49 mm (Min: 0.0, Max: 5.0 mm) after sequential Solaraze® treatment. In patients with AK lesions on the legs as well as in patients with AK lesions on the trunk at start of the study, the size of the AK lesions after sequential Solaraze® treatment was not recorded (ref. chapter 6.9.2).

The physicians rated the general effectiveness of Actikerall® as very good or good in 79.25%, and the general tolerability of Actikerall® as very good or good in 84.01% of the SAF (ref. chapter 6.10.1). Regarding the treatment schedule per week, most of the SAF (41.16%) applied Actikerall® every day (ref. chapter 6.10.1).
According to the physicians, the general effectiveness of Solaraze® was very good or good in 77.93%, and the general tolerability of Solaraze® was very good or good in 89.64 of the patients with sequential Solaraze® treatment (ref. chapter 6.10.2). Regarding the treatment schedule per week, most of the patiens with sequential Solaraze® treatment (51.35%) applied Solaraze® every day (ref. chapter 6.10.2).

Adverse drug reactions related to Actikerall® were recorded for 17 patients (5.78% of the safety population, ref. chapter 6.11.1). Among the non-serious adverse drug reactions (N=16, 5.44% of the safety population), the most frequent symptom

(MedDRA 18.1 preferred terms) was ‘Application site pain’ (N=3, 1.02%). A serious adverse drug reaction related to Actikerall® was recorded for 1 patient (0.34% of the safety population). The patient showed an atypical fibroxanthoma on the left helix. The physician did not provide assessments of seriousness and causal relation. The event was classified as a serious case by the Drug Safety Department of Almirall Hermal GmbH (ref. chapter 6.11.1).

Regarding therapy with Solaraze®, there were no adverse drug reactions related to Solaraze® (ref. chapter 6.11.2).