1 TITLE PAGE

Study Title :	A vehicle-controlled, investigator-blinded, intra-individual comparison to evaluate the safety, tolerability and efficacy of Momegalen® rich cream and ointment in patients with hand and foot eczema and mild to moderate psoriasis
Protocol No.:	071-005
EudraCT No.:	2008-006148-20
Investigational Product:	Mometasone furoate 0.1% rich cream Mometasone furoate 0.1% ointment
Comparator:	Vehicle of Momegalen® 0.1% rich cream Vehicle of Momegalen® 0.1% ointment
Indication:	Hand and foot eczema / mild to moderate psoriasis
Design:	This is a vehicle-controlled double-blinded study to gain evidence of the safety, tolerability and efficacy of Momegalen® rich cream and Momegalen® ointment in the intra-individual comparison to the respective vehicle. Treatment takes place over 21 days.
Development Phase:	II
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Author of Report:	Dr. Kirstin Michaelis-Wittern SCIderm GmbH Esplanade 6 20354 Hamburg Phone:+49 40 554401 114 Fax: +49 40 554401 291
Study Initiation Date:	FPI 03 Feb 2009
Study Completion Date:	LPO 11 Apr 2009
Date of Report:	Final version 08 Jun 2009

This study was performed in compliance with Good Clinical Pratices (GCP), including the archiving of essential documents.

2 SYNOPSIS

Name of Sponsor/Company: GALENpharma GmbH	Volume: Page: 2	*(For National Authority Use Only)*
Name of Finished Product: Mometasone furoate 0.1% rich cream Mometasone furoate 0.1% ointment **Name of Active Ingredient:** Mometasone furoate		

Title of study:	A vehicle-controlled, investigator-blinded, intra-individual comparison to evaluate the safety, tolerability and efficacy of Momegalen® rich cream and ointment in patients with hand and foot eczema and mild to moderate psoriasis
Investigator(s) and related study site(s):	Prof Dr. Ulrich Mrowietz Dr. Silja Domm Dr. Sascha Gerdes Abt. Dermatologie Universitätsklinikum Schleswig-Holstein, Campus Kiel Schittenhelmstr. 7 24105 Kiel Dr. Martin Miehe Dr. Sören Baeblich Dr. Ulrike Serfling Hautarztzentrum Tegel Gorkistr. 3 13507 Berlin
Publication :	Not applicable
Studied period : **Date of first enrolment:** 03 Feb 2009 **Date of last completed:** 11 Apr 2009	**Phase of development:** Phase II
Objectives:	Primary objective was to gain evidence of the tolerability and safety of Momegalen® rich cream and Momegalen® ointment compared to a vehicle, assessed by the nature, severity and frequency of AEs/SAEs and their relationship to study medication. The secondary objectives were to gain evidence of the tolerability and safety of Momegalen® rich cream and Momegalen® ointment by the assessment of vital signs and the Clinician's and Subject's Assessment of Local Skin Reaction and Tolerability during a 3-week treatment. Furthermore the efficacy was assessed by PGA on a 6-point Likert-scale.

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Methodology: This was a multicentre investigator-blinded study to gain evidence of the safety, tolerability and efficacy of Momegalen® rich cream and ointment in the intra-individual comparison to a vehicle. Treatment takes place once daily over 21 days.

Number of patients:	**planned:** 40 **screened:** 41	**randomized:** 41 **completed:** 41	**analysed safety:** safety population 40 **analysed efficacy:** ITT 39

Diagnosis and main criteria for inclusion:

Patients with hand and foot eczema or mild to moderate psoriasis

- Female or male individuals 18 years and above in good general health
- Individuals with mild to moderate plaque-type psoriasis and a BSA < 10
  or
  individuals with the diagnosis of hand and foot eczema (PGA > 2) based on a thorough clinical diagnostic including a patch test and fungal culture performed within the last 12 months
- Individuals with at least two symmetric lesions with a nominal diameter of at least 2 cm

Test product, dose and mode of administration, batch number:

Mometasone furoate 0.1% rich cream	Once-daily application (total max. dose 50 g)	cutaneous	Batch no.: 08511
Mometasone furoate 0.1% ointment	Once-daily application (total max. dose 50 g)	cutaneous	Batch no.: 08512

Duration of treatment: 21 days

Reference therapy:

Vehicle of Momegalen® 0.1% rich cream	Once-daily application (total max. dose 50 g)	cutaneous	Batch no.: 08511
Vehicle of Momegalen® 0.1% ointment	Once-daily application (total max. dose 50 g)	cutaneous	Batch no.: 08512

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Criteria for evaluation:

All randomized patients were summarized in the description of the study population. Efficacy analyses were based on the ITT population. 2 randomized patients were excluded from the ITT population. 40 patients out of 41 enrolled patients were included in safety analyses.

Efficacy: The efficacy parameter for therapeutic response was the PGA assessed respectively to the different diseases at visit 1 (day 0), visit 2 (day 7) and visit 3 (day 21).

Safety: Tolerability and safety of Momegalen® were assessed by AEs, their nature, frequency, severity and relationship to study medication, by vital signs and by the Clinician's Global Assessment of Local Skin Reaction and Tolerability as well as by the Subject's Global Assessment of Local Skin Reaction and Tolerability.

Statistical methods:

The Statistical Analysis Plan defined the statistical analyses for all study evaluations.

The efficacy analysis was performed descriptively using means, median, standard deviations and range.
Safety analyses of the nature, severity and relationship of AEs to study medication were summarized by preferred term and system-organ class and presented in frequencies and percentages broken down by treatment group. Clinician's Global Assessment of Local Skin Reaction and Tolerability as well as the Subject's Global Assessment of Local Skin Reaction and Tolerability were analyzed descriptively. Variables were summarized according to the level of measurement by means and standard deviation or median and range (maximum and minimum) respectively. Vital signs were analyzed by showing abnormal values.

Summary - Conclusions:

Safety Results: The safety and tolerability of both investigational products was good throughout the study. No AE occurred under the treatment with Momegalen® ointment. The vast majority of both related and unrelated/unlikely related AEs under treatment with Momegalen® rich cream were documented as mild, only one AE was reported as moderate. The Clinician's and the Subject's Global Assessment of the Local Skin Reaction and Tolerability showed a very good tolerability for both treatment arms.

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Efficacy Results:
Under treatment with Momegalen® ointment and Momegalen® rich cream a continuous decrease by means of PGA was observed. Under treatment with the respective vehicle a lower reduction in mean was evaluated. Main changes in PGA were evaluated between visit 1 and visit 2.

Conclusion:
The results in this study indicated that treatment with Momegalen® ointment and Momegalen® rich cream show a good tolerability and safety. Local side effects such as irritation and pruritus were of mild intensity and short duration and were comparable to side effects observed under treatment with the well-known active ingredient mometasone furoate. No serious adverse events occurred. The degree of efficacy demonstrated in this study show evidence of the therapeutic value of Momegalen® ointment and Momegalen® rich cream used in the treatment of inflammatory skin diseases.

Date of the Report: Final version 08 Jun 2009