1 TITLE PAGE

Study Title :	A prospective placebo-controlled intraindividual dose-finding study of Mometasone furoate cutaneous spray (solution) in patients with contact allergies
Protocol No.:	071-003/08
EudraCT No.:	2008-004326-16
Investigational Product:	Mometasone furoate cutaneous spray (solution) (0.002%, 0.01%, 0.05%, 0.1%)
Comparator:	Placebo Ecural® 0.1% solution
Indication:	Contact allergy
Design:	This study is a monocenter, randomized placebo-controlled double-blind intraindividual dose-finding study in subjects with contact allergies over a treatment period of 7 days.
Development Phase:	II a
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Study Initiation Date:	FPI 10-NOV-2008
Study Completion Date:	LPO 26-NOV-2008
Date of Report:	Final version 25-AUG-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 cutaneous spray (solution) [0.002%, 0.01%, 0.05%, 0.1%] **Name of Active Ingredient:** Mometasone furoate		

Title of study:	A prospective placebo-controlled intraindividual dose-finding study of Mometasone furoate cutaneous spray (solution) in patients with contact allergies
Investigators:	Prof. Dr. Kristian Reich Dr. Kaweh Shakery Leyla Brocatti Esplanade 6 20354 Hamburg
Study centre:	SCIderm Clinics Esplanade 6 20354 Hamburg
Publication :	Not applicable
Studied period : **Date of first enrollment:** 10-NOV-2008 **Date of last completed:** 26-NOV-2008	**Phase of development:** Phase II a
Objectives:	Primary objective was to gain first evidence of the efficacy of mometasone furoate cutaneous spray (solution) in comparison with Ecural® 0.1% solution and a placebo assessed by the Local Eczema Score. The secondary objective was to evaluate the safety assessed by the Clinician's Global Assessment of Local Skin Reaction and Tolerability.
Methodology:	This was an exploratory randomized prospective investigator-blinded intraindividual, dose-finding study to evaluate the efficacy and safety of mometasone furoate cutaneous spray (solution) in four different concentrations in comparison with Ecural® 0.1% solution and a placebo. Treatment took place over seven days on six test areas with an at least twofold positive reaction to a previously-triggered standardized allergen in subjects with an at least twofold positive reaction in a patch test performed within the last two years.

Name of Sponsor/Company: GALENpharma GmbH **Name of Finished Product:** Mometasone furoate cutaneous spray (solution) [0.002%, 0.01%, 0.05%, 0.1%] **Name of Active Ingredient:** Mometasone furoate	Volume: Page: 3	*(For National Authority Use Only)*

Number of patients:	**planned:** 15 **screened:** 18	**randomized:** 17 **completed:** 17	**analysed safety:** safety population 17 **analysed efficacy:** ITT population 17

Diagnosis and main criteria for inclusion: Patients with contact allergies

- Female or male subjects ≥ 18 years and ≤ 75 years of age in good general health
- Patients with a documented at least twofold positive ('++') patch reaction to one of the standard allergens in a patch test performed according to the guideline of the German Contact Allergy Group (DKG) version 05/2007 (http://www.uni-duesseldorf.de/awmf/ll/013-018.htm) in the last two years

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

Mometasone furoate cutaneous spray (solution) 0.002%	1 spray stroke (contains approx. 40 mg solution)	cutaneous	Batch no.: 810288-21
Mometasone furoate cutaneous spray (solution) 0.01%	1 spray stroke (contains approx. 40 mg solution)	cutaneous	Batch no.: 709754-21
Mometasone furoate cutaneous spray (solution) 0.05%	1 spray stroke (contains approx. 40 mg solution)	cutaneous	Batch no.: 709157-21
Mometasone furoate cutaneous spray (solution) 0.1%	1 spray stroke (contains approx. 40 mg solution)	cutaneous	Batch no.: 709753-21

Duration of treatment:	Clinical phase, total	8 (9) days
	Elicitation of patch test reaction	48 (72) hours
	Treatment	7 days
	Follow-up (optional)	2 days

Reference therapy:

Mometasone furoate cutaneous spray (solution) placebo	1 spray stroke (contains approx. 40 mg solution)	cutaneous	Batch no.: 709158-21
Ecural® Lsg. 0.1%	43 µl solution	cutaneous	Batch no.: 080125

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Criteria for evaluation:

All randomized patients were summarized in the description of the study population. Efficacy analyses were based on all randomized patients who received at least one dose of each test drug and satisfied all major entry criteria. All patients who were enrolled were included in safety analyses.

Efficacy:

The efficacy of mometasone furoate cutaneous spray (solution) in comparison with Ecural® 0.1% solution and a placebo were evaluated by the Local Eczema Score.

Safety:

The safety evaluation included the Clinician's Global Assessment of Local Skin Reaction and Tolerability and the assessment of AEs/SAEs.

Statistical methods:

The Statistical Analysis Plan defined the statistical analyses for all study evaluations.
The efficacy parameter was analyzed on the ITT population. Efficacy analyses were performed on a descriptive level using means with intervals of confidence at the 5% level of significance and standard deviations.
The safety parameters were analyzed on the safety population. The safety analyses were performed on a descriptive level using medians and quartiles.

Summary – Conclusions

Efficacy results:

The means of local eczema scores continuously reduced during the course of the treatment.

Throughout the study Ecural® achieved the best outcome with a mean of 0.52 $\pm$ 0.36. In comparison mometasone fuorate cutaneous spray 0.1% with a mean of 0.61 $\pm$ 0.30 and mometasone fuorate cutaneous spray 0.05% with a mean of 0.54 $\pm$ 0.30 achieved comparable outcomes at visit 8 (day 8/9).
Placebo treatment showed a mean of 0,69 $\pm$ 0.39 at visit 8, while mometasone fuorate cutaneous spray 0.002% with a mean of 0,74 $\pm$ 0.28 and mometasone fuorate cutaneous spray 0.01% with a mean of 0,71 $\pm$ 0.34 achieved at visit 8 results that were comparable to the placebo results.

Safety results:

All six different treatments were generally well tolerated throughout the study. No AEs/SAEs occurred and the investigational products showed a very good tolerability.

Conclusion:
There is good evidence from the present study that a novel cutaneous spray (solution) containing 0.05% or 0.1% mometasone furoate has strong anti-inflammatory properties in a cutaneous delayed-type hypersensitivity reaction (CHS) model of cutaneous inflammation in combination with a good tolerability profile. In particular, the cutaneous spray (solution) containing 0.05% or 0,1% of mometasone furoate in a lipohilic carrier had a clinical efficacy comparable to Ecural® 0.1% solution while containing the same or half of the amount of the active ingredient. Mometasone fuorate cutaneous spray containing 0.01% or less of the active ingredient showed a clinical efficacy that was comparable to the effects of the administered placebo solution.

Date of the report: 25-AUG-2009