

## **KURZPROTOKOLL** **MC2-01-C6**

<b>Wissenschaftl. Titel</b>	A Randomised, Open-label, Maximal Use Trial, Evaluating the Pharmacokinetic Profile of Active Ingredients and Their Metabolites After Application of MC2-01 Cream Compared With Active Comparator in Subjects With Extensive Psoriasis Vulgaris
<b>Kurztitel</b>	MC2-01-C6
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Haut: Schuppenflechte (Psoriasis)
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Have provided written informed consent</li><li>- Generally healthy males or non-pregnant females, of any race or ethnicity, who are at least 18 years of age at the time of screening</li><li>- At Visit 1/Day 0, have a clinical diagnosis of plaque psoriasis (psoriasis vulgaris) of at least 6 months duration involving scalp and body (trunk and/or limbs) that is amenable to topical treatment with a maximum of 100 g of trial medication per week</li><li>- Have a Physician's Global Assessment [PGA] of severity of at least moderate on the trunk, limbs and/or scalp, at Visit 1/Day 0</li><li>- Have a treatment area between 20% and 30% of the body surface area [BSA] on the trunk, limbs and/or scalp, excluding psoriatic lesions on the face, genitals, and intertriginous areas, at Visit 1/Day 0</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Current diagnosis of unstable forms of psoriasis</li><li>- Other inflammatory skin disease in the treatment area</li><li>- Pigmentation, extensive scarring, pigmented lesions or sunburn in the treatment areas</li><li>- Planned exposure to natural or artificial sunlight</li><li>- Phototherapy and ultraviolet B radiation within 4 weeks prior to Visit 1/Baseline and during the trial</li><li>- Current or past history of hypercalcemia, vitamin D toxicity, severe renal insufficiency, or severe hepatic disorders</li><li>- Oral calcium supplements, vitamin D supplements, bisphosphonates or calcitonin within 4 weeks prior to Visit 1/Day 0 during the trial period</li><li>- Planned initiation of, or changes to concomitant medication that could affect calcium metabolism during the trial</li><li>- Planned initiation of, or changes to, concomitant estrogen therapy during the trial</li><li>- Strong systemic cytochrome P450 3A4 (CYP 3A4) inhibitors within 4 weeks prior to Visit 1/Day 0 and during the trial period</li><li>- Use of topical treatments, except for emollients and non-medicated shampoos, with a possible effect on psoriasis within 2 weeks prior to Visit 1/Day 0 and during the trial period</li><li>- Systemic treatment with biological therapies</li><li>- Initiation of, or expected changes to, concomitant medication that may affect psoriasis during the trial period</li><li>- Depression and endocrine disorders known to affect cortisol levels or HPA axis integrity, non-nocturnal sleep patterns</li><li>- Systemic medication that suppresses the immune system within 4 weeks prior to the Visit 1/Day 0 and during the trial period</li><li>- Clinical signs of skin infection with bacteria, viruses, or fungi</li><li>- Known human immunodeficiency virus [HIV] infection;</li><li>- Known or suspected of hypersensitivity to any component of the test product or reference product</li></ul>

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- Any chronic or acute medical condition that may pose a risk to the safety of the subject, or may interfere with the assessment of safety or efficacy in this trial

**Alter** 18 Jahre und älter  
**Sponsor** MC2 Therapeutics  
**Registrierung in anderen Studienregistern** ClinicalTrials.gov NCT03462927 (primäres Register)  
EudraCT 2018-000685-12