

## **Method**

### *Study Design*

This open-label, prospective, multicentre, observational, non-controlled, non-interventional study was conducted in compliance with the German Medicinal Products Act (AMG, § 4 (23), sentence 3), was approved by the Ethics Committee of Schleswig-Holstein, and the positive opinion (BT-Drs.17/13770) was notified to the respective German regulatory bodies.

### *Inclusion and Exclusion Criteria*

Adult patients ( $\geq 18$  years of age) with at least mild psoriasis vulgaris (as per the IGA, 5-point scale) [16] and with psoriasis lesions on the trunk and/or on the extremities could be enrolled when already foreseen to be treated with the Cal/BD aerosol foam before enrolment. Patients with pre-existing contra-indications or known allergies against the Cal/BD aerosol foam or one of its ingredients, as well as patients under systemic antipsoriatic therapy or UV therapy within 2--4 weeks prior to enrolment or patients with severe ( $>30\%$  of BSA) or special forms of psoriasis (e.g. erythrodermic psoriasis or pustular psoriasis) were excluded.

### *Objectives and Variables*

The primary objective of the study was to determine the efficacy, tolerability, and convenience of application during and after 4 weeks of therapy with Cal/BD aerosol foam in daily practice conditions. Psoriasis severity was assessed before and 4 weeks after treatment with the Cal/BD aerosol foam by the investigators, using a 5-point IGA scale [16], the affected BSA and the PASI. Any adverse drug reaction was documented at each visit or if reported spontaneously. Patients were asked to complete a patient diary with questionnaires regarding their immediate perception of the aerosol foam and regarding the severity of their psoriasis after 1, 2, and 4 weeks using a 5-point patient global assessment scale analogous to the IGA. Individual symptoms of psoriasis (pruritus, sleep loss due to pruritus, desquamation, erythema, xerosis) were quantified by a 10-point numerical rating scale. At baseline and after 4 weeks of treatment, quality of life was measured using the DLQI questionnaire, and satisfaction with the efficacy, tolerability, and application of the preceding therapy as well as of the Cal/BD aerosol foam was assessed.

### *Statistics*

According to the non-interventional design, statistical analyses were primarily descriptive and explorative. A statistical hypothesis was not stated in the observation protocol.

The following populations were analysed:

- The intention-to-treat (ITT) population included all patients who had provided a written informed consent for the use of their data in this study ( $n = 410$ )
- The safety population is a subgroup of the ITT population and includes only patients who had applied the Cal/BD aerosol foam at least once ( $n = 391$ )
- The efficacy population is a subgroup of the safety population and includes all patients for whom at least 1 efficacy variable had been documented ( $n = 390$ )

When calculating absolute, relative, and adjusted proportions, patients with missing details were excluded. Statistical tests used were the Wilcoxon signed-rank test, a non-parametric test applied to compare repeated measurements of a single sample, and the Bhapkar test of marginal homogeneity, to compare the marginal distribution of contingency tables.