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# Significant efficacy and tolerability of the ivy leaves dry extract EA 575® (Prospan® Cough Liquid) vs. placebo in adults with acute coughs

**Study title:**
A randomized, controlled, double-blind, multi-center trial to evaluate the efficacy and safety of a liquid containing ivy leaves dry extract (EA 575®) vs. placebo in the treatment of adults with acute cough

**Study design:**
Randomized, placebo-controlled, double-blind, multi-center study

**Patients:**
181 patients aged 18–75 years (89 patients in the verum group, 92 patients in the placebo group)

**Diagnosis:**
Acute cough with prolonged symptoms during the preceding 2–3 days

**Dosage:**
Prospan® Cough Liquid with the ivy leaves dry extract EA 575® based on the recommended dose for adults of 3 x 5 ml daily or a placebo with the same dosage

**Treatment and observation period:**
- 7 days of treatment (Visit 1 – Visit 5)
- 14 days of observation (Visit 6)

**Primary endpoint for efficacy:**
- Subjective perception of Cough Severity (CS) by the patient throughout the duration of treatment lasting 7 days (V1 – V5), ascertained using the Visual Analog Scale (VAS, area-under-the-curve $AUC_{0\text{-}168\ h}$)

**Secondary endpoints for efficacy:**
- Subjectively perceived Cough Severity (CS) throughout the entire observation period, ascertained using the Visual Analog Scale
- Changes in the Bronchitis Severity Score (BSS) between V1 and subsequently V2 – V5
- Subjectively perceived Cough Severity (CS) throughout the duration of treatment lasting 7 days (V1 – V5), ascertained using the Verbal Category Descriptive Score (VCD Score)
- Assessment of the global treatment efficacy by the physician and patient at V5 and V6, ascertained using the Global Efficacy Assessment (GEA)

**Tolerability:**
- Tolerability of Prospan® Cough Liquid with ivy leaves dry extract EA 575® compared to placebo, ascertained using the number of adverse events (V1 – V6), vital signs (V1, V5 and V6), clinical examination (V1, V5 and V6) and global tolerability assessment (V5 and V6)

**Primary result for efficacy:**
- The Cough Severity (ascertained using VAS) of the patients treated with EA 575® (Prospan® Cough Liquid) significantly improved over the entire duration of treatment compared to the placebo group ($AUC_{0\text{-}168\ h}$, $p < 0.0001$). After only 48 hours a 13% reduction was observed, and after 7 days there was a 69% reduction (Fig. 1)

**Secondary results for efficacy:**
- The subjective Cough Severity ascertained using the VCD Score of the patients treated with EA 575® (Prospan® Cough Liquid) also significantly reduced over the entire duration of treatment compared to the placebo group, at the end of treatment by 60% (Fig. 2).
- The severity of the symptoms recorded by the physician together with the patient (BSS) significantly reduced by 20% in the group of patients treated with EA 575® (Prospan® Cough Liquid) compared to the placebo group after only 48 hours (Fig. 3).
- The global treatment efficacy assessed by the physician and patient (GEA) displayed a statistically significant improvement in symptoms at both assessment times as a result of EA 575® (Prospan® Cough Liquid) compared to placebo ($p = 0.0001$).

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**Tolerability:**

- Very good tolerability of EA 575® (Prospan® Cough Liquid): there were no treatment-related, adverse events

**Other results:**

- There were no interactions with other medicines during intake of EA 575® (Prospan® Cough Liquid)
- The group that received EA 575® (Prospan® Cough Liquid) still displayed a significant advantage with regard to Cough Severity 7 days after the end of treatment compared to the placebo group
- High compliance: over 80% of patients took the medication as prescribed

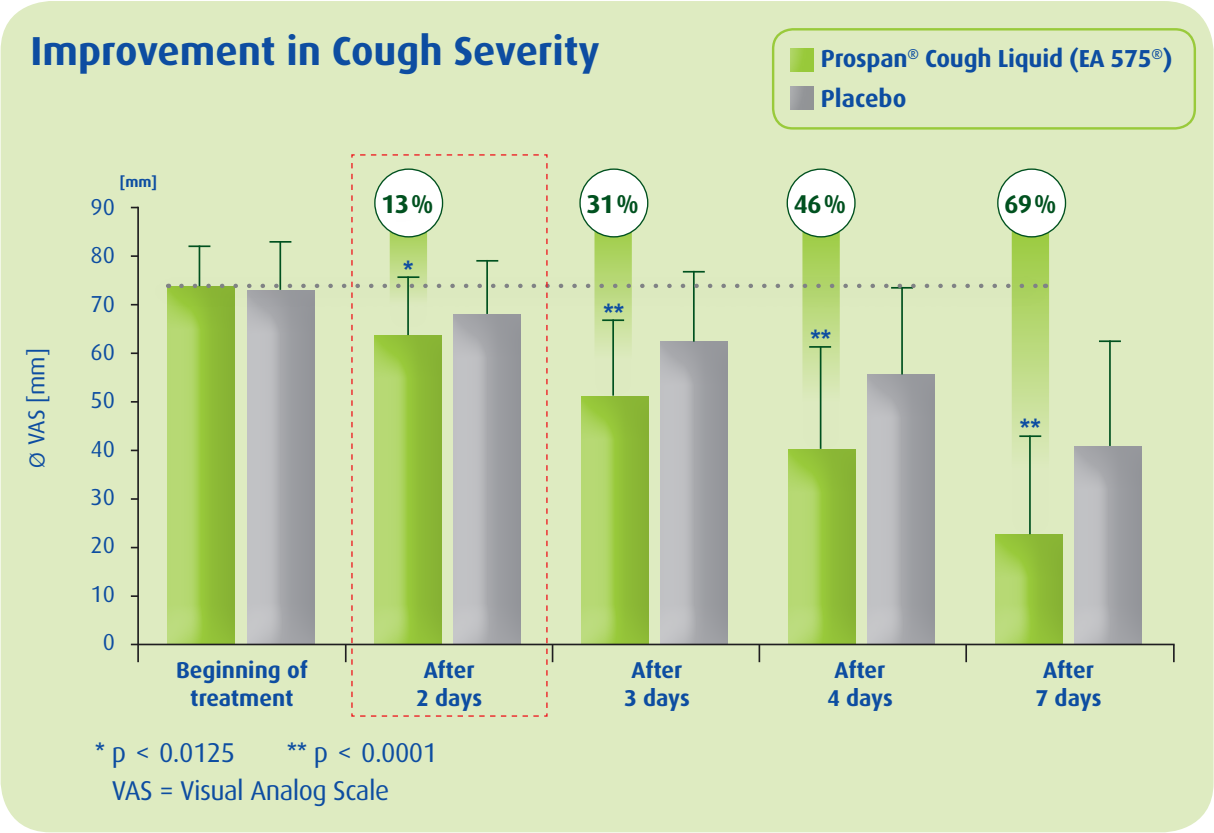


**Fig. 1** Improvement in Cough Severity (VAS) during treatment and compared to placebo

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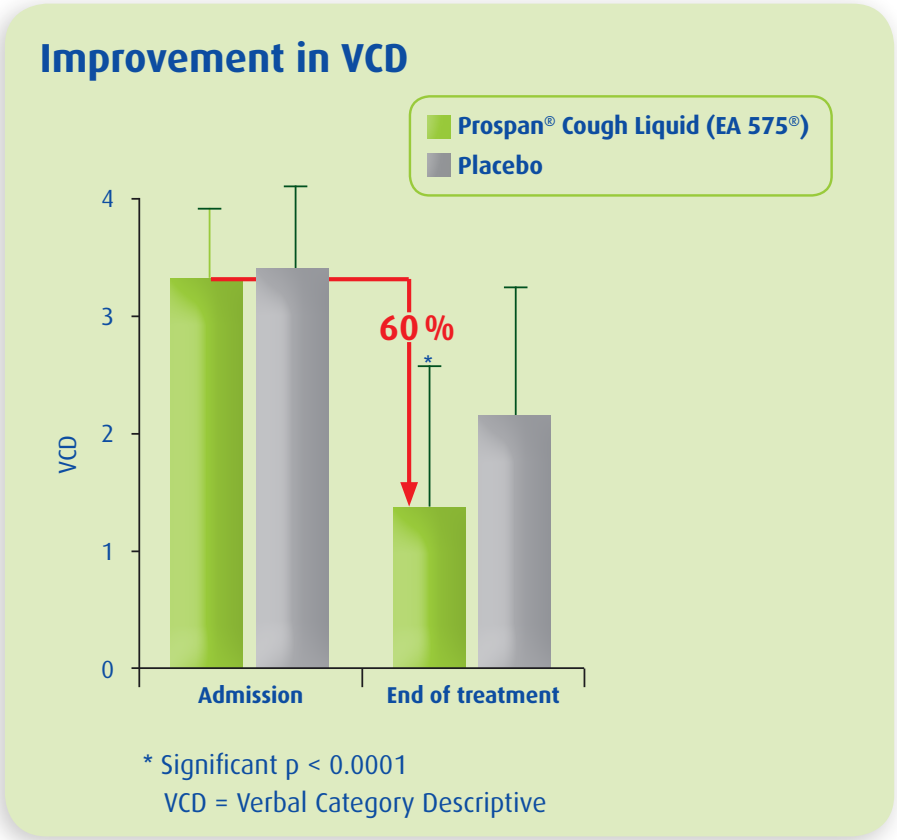


**Fig. 2** Improvement in VCD during observation period and compared to placebo

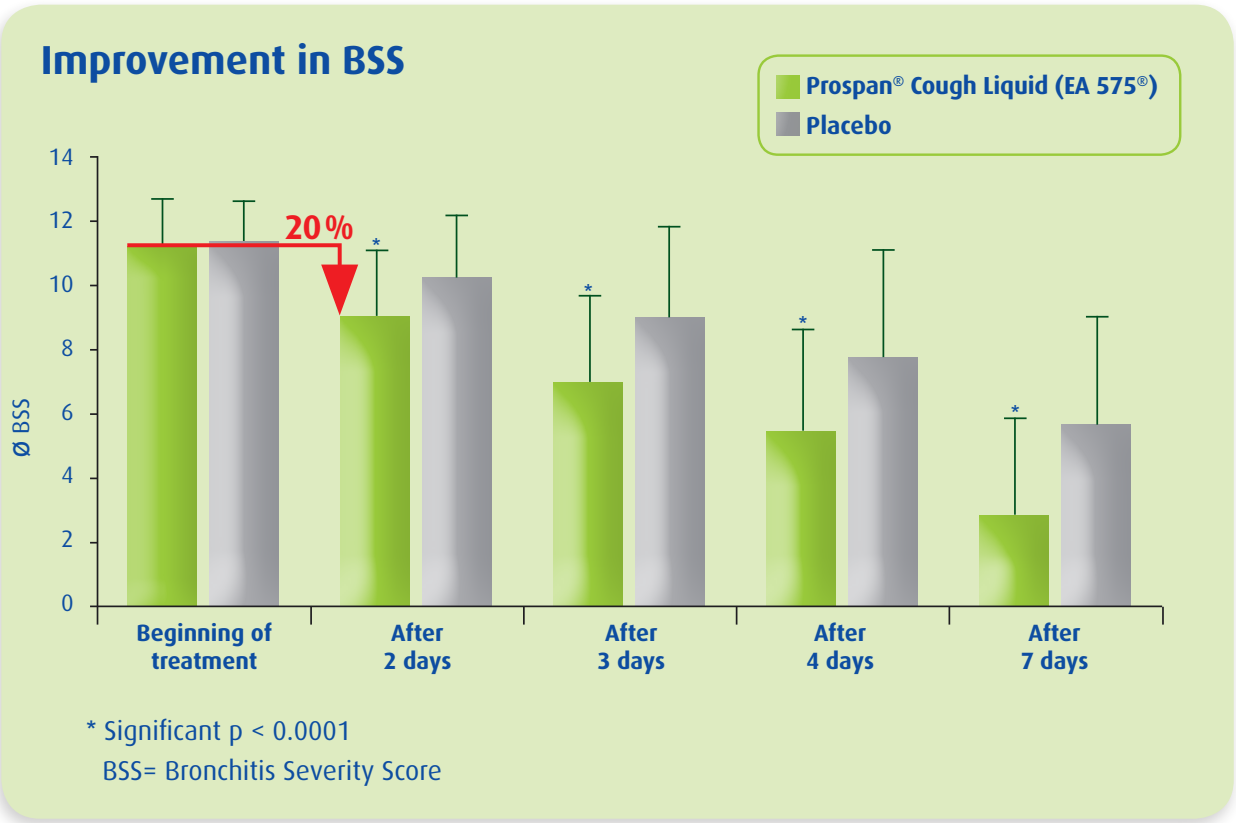


**Fig. 3** Improvement in BSS during treatment and compared to placebo

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## Summary


- Confirmation of the very good efficacy and very good tolerability of EA 575® (Prospan® Cough Liquid) in adult patients with acute coughs.
- The group treated with EA 575® (Prospan® Cough Liquid) displayed a significant improvement in the result for the primary endpoint (patient evaluation of the subjectively perceived Cough Severity using VAS) and also in all results for secondary endpoints (evaluation by physicians and patients).
- The cough-related symptoms significantly reduced during intake of EA 575® (Prospan® Cough Liquid) compared to placebo after only 48 hours (Cough Severity, BSS and VCD).


## Score info

- **BSS Score:** Assessment of the five most important symptoms of illness (cough, mucus production, chest pain, crackles during auscultation, and dyspnea) each on a scale of 0 (non-existent) to 4 (very severe). Summation for the evaluation of the individual symptoms (maximum value of BSS = 20).
- **VAS Scale:** Assessment of subjectively perceived Cough Severity by patients on a scale of 0 (no cough) – 100 (extreme cough).
- **VCD Score:** Assessment of the degree of subjectively perceived Cough Severity in everyday life on a scale of 0 (no cough) to 5 (highly intrusive, continual coughing for 24 hours).
- **GEA Score:** Assessment of the global treatment efficacy (overall effect of treatment and prescribed medication) each on a 5-point Likert scale.


Source: Schaefer A et al., A randomized, controlled, double-blind, multi-center trial to evaluate the efficacy and safety of a liquid containing ivy leaves dry extract (EA 575®) vs. placebo in the treatment of adults with acute cough. Pharmazie 2016; 71(9): 504-509.