

Duration of use

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65. The EMA recommends that oral Echinacea preparations should be used for a limited duration of up to 10 days (EMA, 2014). The German Commission E monographs on Echinacea recommend that internal and external administration of *E. purpurea* and *E. pallida* should not exceed 8 weeks (Blumenthal et al., 1999). No scientific rationale has been provided for the limits on the duration of use. Echinacea preparations have been used for longer durations without any serious adverse effects as described below.

66. The clinical studies involving Echinacea have varying durations from 4-21 days to 4-12 weeks (Ardjomand-Woelkart and Bauer, 2015). The study with the longest duration involved the administration of 800 mg *E. purpurea* whole plant extract twice a day for 6 months to 50 patients (Vonau et al., 2001). The only side effects reported were nausea (n = 4) and diarrhoea (n = 2). The use of *E. purpurea* and *E. angustifolia* root liquid extract for 12 weeks (100 drops daily of a 1:11, 30% ethanolic extract for 5 days a week) was studied in randomized,

double-blind, placebo controlled trial involving 289 patients (n=100 for *E. angustifolia*, n=99 for *E. purpurea*, n=90 for placebo) for the prevention of respiratory tract infections (Melchart, 1998). The side effects reported included minor gastrointestinal symptoms, headache/dizziness, allergic reactions and were similar between treatment arm and placebo (Melchart, 1998).

67. The safety and efficacy of Echinaforce was tested in a large randomised, double-blind, placebo-controlled clinical trial for 4 months. A total of 755 subjects were included and the main criteria for inclusion was that they experience ≥ 2 colds per year. Participants took the equivalent of 2,400 mg of extract a day for illness prevention, but during acute stages of colds the dose was increased to 4,000 mg extract/day. There were no significant differences between the frequencies and the type of adverse effects between treatment and placebo. Haematological and biochemical measures were not significantly different before and after Echinacea treatment and when compared to placebo (Jawad et al., 2012).