

Duration of use

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71. The EMA advises 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). However, some clinical studies (see paragraphs 72–74) report the use of

Echinacea preparations for longer periods. It should be noted that these clinical studies typically involve medicinal Echinacea preparations, which may not be directly comparable to foods or food supplements that are the focus of this assessment.

72. 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 was prospective, placebo controlled, double blinded cross over trial in which participants (n=50) were randomised to receive 6 months of 800 mg Echinaforce (95% *E. purpurea* whole plant extract and 5% *E. purpurea* root extract) twice daily or placebo, followed by the alternate treatment for a further 6 months for reducing the frequency and duration of recurrent genital herpes (Vonau et al., 2001). The only side effects reported were nausea (n = 4) and diarrhoea (n = 2). Pregnancy, or not using effective contraception during the study period, were exclusion criteria for this trial.

73. 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 randomised, 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).

74. The safety and efficacy of Echinaforce was tested in a large randomised, double-blind, placebo-controlled clinical trial for 4 months (Jawad et al., 2012). 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.