



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Opinion of the HMPC on a European Union herbal monograph on *Urtica dioica* L.; *Urtica urens* L., herba

Opinion

The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC and as set out in the appended assessment report, establishes, by a majority of 23 out of 24 votes a revised European Union herbal monograph on *Urtica dioica* L.; *Urtica urens* L., herba which is set out in Annex I.

The divergent position is appended to this opinion.

The Norwegian HMPC member agrees with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States and Norway, together with its Annex I and appendices.

The revised European Union herbal monograph and assessment report will be published on the European Medicines Agency website. They replace those adopted on 4 September 2008.

Amsterdam, 22 January 2025.

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Annex I: European Union herbal monograph (EMA/HMPC/261302/2022)

Appendix I: Assessment report (EMA/HMPC/261303/2022)

Appendix II: Divergent positions

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reason:

Ireland does not support Indication 3) Traditional herbal medicinal product used in seborrhoeic skin conditions.

The diagnosis of seborrhoeic dermatitis is a clinical diagnosis based on the location, appearance, and behaviour of the lesions with the possibility of several differential diagnoses.

We believe this indication would not meet the criteria for a THMP even with the caveat of previous medical diagnosis. We also note the posology is a powdered herbal substance SD=275 mg, 3 times daily DD=825 mg for oral use which is unusual for dermatological conditions such as this one. Treatment of seborrhoeic dermatitis would normally be with topical agents with oral treatment (antifungals) reserved for resistant cases.

Jackie Masterson, HMPC member from Ireland.

Amsterdam, 22 January 2025.