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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL PROPOSAL FOR A CORE-DATA FOR NETTLE LEAF

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Final Proposal for a Core-data on Nettle leaf

The Working Party on Herbal Medicinal Products proposes the following core-data for *Urticae folium*.

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1) Nettle leaf¹

2) Dry extracts prepared with 50% V/V ethanol (8-10:1)

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Herbal medicinal product used as adjuvant in the symptomatic treatment of minor articular pain².

4.2. Posology and method of administration

Dosage

Daily dose for elderly, adults and adolescents over 12 years of age:

Dried drug as infusion: 2 – 4 g in 150 ml 3 to 4 times daily

Dry extracts with 50% V/V ethanol (8-10 : 1) 536 mg, twice daily

Method of administration

Oral use

Duration of use

No restriction but see 4.4 Special warnings and precautions for use.

¹ The herbal drug complies with Deutsches Arzneibuch 2002 and is expected to comply with the European Pharmacopoeia (the Eur. Ph. draft monograph on Nettle leaf has been published in Pharmeuropa 2002; 14: 142-144)

² Decision by majority

4.3. Contraindications

Patients with known hypersensitivity to Nettle should not use Nettle leaf preparations.

4.4. Special warnings and precautions for use

Because there is no experience available, use of this product is not recommended in children below the age of 12 years.

Patients suffering from diabetes should consult their physician before using Nettle leaf preparations.

If symptoms persist or worsen within two weeks, a physician should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

Nettle leaf preparations may interact with antidiabetic treatment.

4.6. Pregnancy and lactation

Because data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

The use of Nettle leaf preparations occasionally causes mild gastrointestinal complaints.

Allergic reactions (e.g. itching, exanthema, hives) may occur rarely.

4.9. Overdose

None reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: ATC code M 05 (other drugs for disorders of the musculo-skeletal-system)

The effects of Nettle leaf preparations have long been recognised empirically but cannot be attributed with certainty to known constituents. The uses are made plausible by information from open pharmacological and clinical studies (level III)³.

³ Points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications (EMEA/HMPWP/23/99)

5.2. Pharmacokinetic properties

No data available.

5.3. Preclinical safety data

Toxicity tests in animals have not given cause for concern within the recommended dosage range.

6. DATE OF COMPILATION

July 2003