The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

4 April 2000
EMEA/HMPWP/21/00

WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

DRAFT PROPOSAL FOR A CORE DATA FOR *DEVIL'S CLAW ROOT*

DISCUSSION IN THE HERBAL MEDICINAL PRODUCTS WORKING PARTY	October 1999 March 2000
RELEASE FOR CONSULTATION BY THE EMEA	May 2000
DEADLINE FOR COMMENTS	August 2000
RE-SUBMISSION TO THE HMPWP	October 2000

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Draft Proposal for a Core-data for Devil's claw root

The Working Group on Herbal Medicinal Products proposes the following core-data for *Devil's claw root*[1] (March 2000).

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[2]

Dried secondary root tubers of Harpagophytum procumbens DC.
Extracts prepared with water

3. PHARMACEUTICAL FORM

Herbal drug preparation in solid or liquid dosage form (to be labelled according to the standard terms published by the European Pharmacopoeia).

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Herbal medicinal product for the symptomatic treatment of minor articular pain.

4.2. Posology and method of administration

For oral use

Adults, elderly and children over 12 years :
single dose : 1,5 to 3 g of drug
decoction or extracts prepared with water corresponding to the same amount of drug.

Two or three times daily.

4.3. Contraindications

Known hypersensitivity to harpagophytum.

4.4. Special warning and precautions for use

Please note that the Patient Leaflet invites the patient to seek medical advice if symptoms persist or worsen , e.g. in case of redness, swelling or overheating of joins.

Serious underlying diseases e.g.rheumatoid arthritis require medical advice before treatment.

Because there is no experience available, the use is not recommended in children younger than 12 years of age.

- As a general precaution, patients with gastric or duodenal ulcer should not use devil's claw preparations.

[1] The herbal drug complies with European Pharmacopoeia

[2] The declaration of all active substances should be done in accordance with the Note for Guidance on quality of herbal medicinal products (type A.1.i or type A.2.1) as revised by the Ad Hoc Working Group on Herbal Medicinal Products

4.5. Interaction with other medicinal products and other forms of interaction

None reported.

4.6. Pregnancy and lactation

Because no experimental data or clinical observation on the use during pregnancy and lactation are available, this medicine should not be used during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

None reported

4.8. Undesirable effects

Mild gastro-intestinal disturbances and cutaneous or allergic reactions are common.
If allergic reaction occurs, the treatment should be stopped.

4.9. Overdose

None reported.

5. PHARMACOLOGICAL PROPERTIES

Pharmaco-therapeutic group : MUSCULO-SKELETAL SYSTEM
ATC code : M01AX : Other antiinflammatory / antirheumatic agents, non-steroids

5.1. Pharmacodynamic properties

Anti-inflammatory effects of Devil's claw have long been recognised empirically but cannot be attributed with certainty to any known constituents. The contribution of harpagoside has to be clarified. The use is made plausible by clinical data even if pharmacological studies show no antiinflammatory or analgesic effect by oral route.
Level of evidence : IV

5.2. Pharmacokinetic properties

No data available

5.3. Preclinical safety data

Available data show a low short-term toxicity. However long-term study and genotoxicity evaluation are lacking.