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

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL PROPOSAL FOR A CORE DATA FOR CALENDULA FLOWER

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Final Proposal for a Core-data for Calendula flower (*Calendula officinalis* L.)

The Working Party on Herbal Medicinal Products proposes the following core-data for *Calendula flower* (March 2003).

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Calendula flower[1]
Tincture 1:5, prepared with ethanol 90 %
In ointments: Fluid extracts (2 - 5 %), prepared with ethanol 40 %

3. PHARMACEUTICAL FORM

Herbal drug preparation in liquid or semi-solid dosage forms for topical use.
The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) or the oral mucosa, and as an aid in healing of minor wounds.

4.2. Posology and method of administration

Dosage

For topical herbal medicinal products the posology has to be assessed on an individual basis. The following posologies are well established and documented:

Infusion for topical application: 1 - 2 g of Calendula flower / 150 ml
The infusion is used as such on the skin or oral mucosa.

Tincture 1 : 5, prepared with ethanol 90 %:
For the treatment of wounds and inflammation of the skin, the tincture is usually diluted at least 1 : 3 with freshly boiled water.

Ointment: 2 - 5 % of fluid extract, prepared with 40 % ethanol.

Method of administration

Topical application, 2 to 3 times daily

[1] The herbal drug complies with European Pharmacopoeia

Duration of use

No restriction.

4.3. Contraindications

Known hypersensitivity to members of the Asteraceae (also known as Compositae) family.

4.4. Special warning 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. Notwithstanding this, there are no objections to the cutaneous use in children.

If symptoms persist or worsen after 2 weeks, a physician should be consulted.

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

None reported.

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.
Notwithstanding this, there are no objections to the cutaneous use during pregnancy and lactation. Calendula preparations are not appropriate for use against sore nipples.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

In very rare cases allergic reactions may occur.

4.9. Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Preparations for treatment of wounds and ulcers,
ATC code: D03

The anti-inflammatory effect of Calendulae flos has been reported in the croton oil ear test in mice in which a CO_2 extract showed a more pronounced oedema inhibition than a 70 % hydro-alcoholic extract. Triterpenoids (faradiol esters) have been reported to be the most important anti-inflammatory principle of the CO_2 extract in this model, the effect of free faradiol being comparable to that of indometacin at comparable amounts.

Isolated polysaccharides from Calendula flower were found to stimulate phagocytosis of human granulocytes. Moreover various hydro-alcoholic extracts showed antimicrobial activity in vitro.

The use of the product is made plausible by evidence obtained from expert committee reports or opinions and/or clinical evidence of respected authorities.
Level of evidence: level IV

5.2. Pharmacokinetic properties

No data available.

5.3. Preclinical safety data

The acute and repeated dose toxicity of Calendula flower extracts is low. Reproduction toxicity studies are lacking. Six saponins from Calendula flower were non-mutagenic in the Ames test. Limited long-term carcinogenicity studies in rats and hamsters did not give evidence of a carcinogenic effect of Calendula flower extract. The sensitising potential of Calendula extract is low.

6. Date of compilation