



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 POSITION STATEMENT ON CHAMOMILLA CONTAINING
HERBAL MEDICINAL PRODUCTS**

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Final Position statement on Chamomilla containing herbal medicinal products

Introduction

In 1992, the CPMP Herbal Medicinal Products Working Party (HMPWP) examined literature on the risk of anaphylactic reactions associated with the consumption of herbal medicinal products containing *Chamomilla recutita* (L.) Rauschert. Following consultation with the CPMP Pharmacovigilance Working Party, the HMPWP prepared a proposal for the amendment of the labelling of *Chamomilla recutita* containing herbal medicinal products to reflect recent findings.

Recommendation

The following amendment to the SPC of *Chamomilla recutita* containing herbal medicinal products is proposed:

Under section 4.8 Undesirable effects

“Hypersensitivity reactions to (german) chamomille (e.g. contact dermatitis) are very rare. **Some cases of anaphylactic shock or asthma have been reported.** Cross reactions may occur even in people with allergy to compositae (e.g. artemisia/mugwort)”.

References

- Fatal outcome of anaphylaxis to chamomile-containing enema during labor: A case study (*Jensen-Jarolim E et al.* (1998) *J Allergy Clin. Immunol.* 102; 1041-1042)
- Anaphylaxis to chamomile: clinical features and allergen cross-reactivity (*Reider N et al.* (2000) *Clinical and Experimental Allergy*: 30; 1436-1443)
- Asthma bronchiale durch inhalation mit Echter Kamille (*Chamomilla recutita*) (*Senff H et al.* (1989) *Allergologie*: 12(2); 51-53)
- Allergic and systemic contact dermatitis from *Matricaria chamomilla* tea (*Rodriguez-Serna M et al.* (1998) *Contact Dermatitis*: 39,4; 192-193)
- Anaphylactic reaction after the ingestion of chamomile tea: a study of cross-reactivity with other composite pollens (*Subiza J et al.* (1989) *J. Allergy Clin. Immunol.*: 84,3; 353-358).