



European Medicines Agency
Evaluation of Medicines for Human Use

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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

**PUBLIC STATEMENT ON CHAMOMILLA CONTAINING HERBAL MEDICINAL
PRODUCTS**

DISCUSSION IN THE HMPC	January 2005 March 2005
RELEASE FOR CONSULTATION	April 2005
DEADLINE FOR COMMENTS	June 2005
REDISCUSSION IN WORKING PARTY ON MONOGRAPHS AND LIST (MLWP)	March 2006
ADOPTION BY HMPC	8 March 2006

Public Statement on Chamomilla containing herbal medicinal products

Introduction

In 2002, 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”

- Cutaneous preparations in semi-solid forms (cream, gel, ointment, etc.) for cutaneous use:

“Hypersensitivity reactions to German chamomile (e.g. contact dermatitis) are very rare. Cross reactions may occur in people with allergy to compositae (e.g. artemisia/ mugwort)”.

- Oral preparations, oromucosal preparations or preparations for inhalation in liquid forms (oral liquid, infusion, oromucosal spray or drops etc.) for internal use (oral use, inhalation use, oromucosal use, vaginal/rectal use):

“Hypersensitivity reactions to (German) chamomile (e.g. contact dermatitis) are very rare. Cross reactions may occur in people with allergy to compositae (e.g. artemisia/mugwort). Very rarely severe allergic reactions (anaphylactic shock, asthma, facial oedema and urticaria) following internal use have been reported”.

References

- Florido-Lopez et al. Allergy to natural honeys and camomile tea. *Int Arch Allergy Immunol*; 108: 170-174, 1995.
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- Jensen-Jarolim E et al. Fatal outcome of anaphylaxis to camomile-containing enema during labor: A case study. *J Allergy Clin. Immunol*: 102; 1041-1042, 1998.
- Jovanovic M, Poljacki M, Duran V, Vujanovic L, Sente R, Stojanovic S. Contact allergy to Compositae plants in patients with atopic dermatitis. *Med Pregl.*; 57 (5-6):209-18, 2004.