



European Medicines Agency
Evaluation of Medicines for Human Use

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

**POSITION STATEMENT ON THE CONCOMITANT USE
OF LAXATIVE BULK PRODUCERS
WITH MEDICINAL PRODUCTS AGAINST DIARRHOEA**

DISCUSSION IN THE HMPWP	April, June 2004
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Position statement on the concomitant use of laxative bulk producers with medicinal products against diarrhoea

Recommendation

The HMPWP published the following proposals for core-data for laxative bulk producers:

- Final proposal for a core-data for Psyllium seed (HMPWP/13/00), March 2003;
- Final proposal for a core-data for Ispaghula seed (HMPWP/14/00), March 2003;
- Final proposal for a core-data for Ispaghula husk (HMPWP/15/00), March 2003;
- Final proposal for a core-data for Linseed (HMPWP/244/03), December 2003.

The HMPWP would like to recommend that the labelling of herbal medicinal products containing laxative bulk producers include a statement on the risk of interaction with drugs known to inhibit gastrointestinal propulsive motility.

The following statement is proposed for inclusion in section 4.5 'Interaction with other medicinal products and other forms of interaction' of the SPC of these medicinal products:

“In order to decrease the risk of gastrointestinal obstruction, [product name] should not be used concomitantly with medicinal products against diarrhoea, which inhibit the peristaltic movement (e.g. loperamide)”.