

10 July 2015 EMA/HMPC/332849/2015 Committee on Herbal Medicinal Products (HMPC)

Herbal medicine: summary for the public

# Agrimony

*Agrimonia eupatoria* L., herba

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of agrimony. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing agrimony.

This summary is not intended to provide practical advice on how to use medicines containing agrimony. For practical information about using agrimony medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

#### What is agrimony?

Agrimony is the common name for the flowering tops of the plant *Agrimonia eupatoria* L. The plant is cultivated or gathered to obtain the plant parts for medicinal use.

Agrimony preparations are obtained by comminuting (reducing into tiny pieces) the dried plant parts. These may also be used to prepare liquid extracts with water and alcohol.

Herbal medicines containing agrimony are usually available as herbal teas to be drunk, or as gargles. They are also available as liquids to be applied to the skin or used as a bath additive.

Agrimony can also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

#### What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that, on the basis of its long-standing use, agrimony can be taken by mouth for the relief of mild diarrhoea, or used as a gargle to relieve mild inflammation of the mouth and throat. It can also be applied to the skin for relief of minor inflammation and small superficial wounds.

Agrimony should only be used in adults and children over the age of 12 years. A doctor or a qualified healthcare practitioner should be consulted if diarrhoea persists for more than 3 days during



treatment, or if mouth, throat or skin symptoms persist for more than a week during treatment. Detailed instruction on how to take agrimony medicines and who can use them can be found in the package leaflet that comes with the medicine.

## What evidence supports the use of agrimony medicines?

The HMPC conclusions on the use of agrimony medicines for the relief of mild diarrhoea, mild inflammation of the mouth and throat, skin inflammation and wounds are based on their 'traditional use' in these conditions. This means that, although there is insufficient evidence from clinical trials, the effectiveness of these herbal medicines is plausible and there is evidence that they have been used safely in this way for at least 30 years (including at least 15 years within the EU). Moreover, the intended uses do not require medical supervision.

The HMPC noted the lack of clinical studies with agrimony, but took into account the well documented use of this herbal medicine for the above uses. For further information, see the HMPC assessment report.

## What are the risks associated with agrimony medicines?

At the time of the HMPC assessment, no side effects had been reported with these medicines.

Further information on the risks associated with agrimony medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: <a href="mailto:ema.europa.eu/Find medicine/Herbal medicines for human use">ema.europa.eu/Find medicine/Herbal medicines for human use</a>.

## How are agrimony medicines approved in the EU?

Any applications for the licensing of medicines containing agrimony have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of agrimony medicines in EU Member States should be obtained from the relevant national authorities.

#### Other information about agrimony medicines

Further information on the HMPC assessment of agrimony medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: <a href="mailto:ema.europa.eu/Find medicine/Herbal medicines for human use">ema.europa.eu/Find medicine/Herbal medicines for human use</a>. For more information about treatment with Agrimony medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.