



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 May 2019
EMA/163216/2019

Oat grain

Avena sativa L., fructus

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

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

What is oat grain?

Oat grain is the common name for the seeds of the plant *Avena sativa* L.

The HMPC conclusions only cover oat grain preparations that are obtained by drying and comminuting (reducing into tiny pieces) the grains and preparing from that a so-called 'colloidal oatmeal' by finely grinding the oats and boiling them.

Herbal medicines containing these oat grain preparations are usually used in semi-solid forms to be applied to the skin and in solid forms as bath additives.

Oat grain preparations may 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, this oat grain preparation can be used for minor skin inflammation such as sunburn and as an aid in healing minor wounds.

Oat grain medicines may be used in adults and children. If symptoms last longer than 1 week when using the medicine, a qualified health practitioner should be consulted. Detailed instructions on how to use oat grain medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of oat grain medicines?

The HMPC conclusions on the use of these oat grain medicines for skin inflammation and minor wounds are based on their 'traditional use'. 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 use does not require medical supervision.

In its assessment, the HMPC also considered clinical studies with oat grain medicines. Although a possible effect on skin inflammation was observed, firm conclusions could not be drawn since the studies involved a range of conditions, different oat grain preparations and both treatment duration and outcomes measured were variable. Therefore, the HMPC conclusions on the use of these oat grain medicines are based on their long-standing use.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with oat grain medicines?

Skin reactions have been reported with oat grain medicines in patients with allergies and patients with contact dermatitis (itchy, red and dry skin). The frequency is not known.

Further information on the risks associated with these oat grain medicines, including the appropriate precautions for their safe use, can be found in the monograph, which is published on the Agency's website under the section 'Documents': ema.europa.eu/medicines/herbal/avenae-fructus.

How are oat grain medicines approved in the EU?

Any applications for the licensing of medicines containing oat grain 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 oat grain medicines in EU Member States should be obtained from the relevant national authorities.

Other information about oat grain medicines

Further information on the HMPC assessment of oat grain medicines, including details of the Committee's conclusions, can be found under the section 'Documents' on the Agency's website: ema.europa.eu/medicines/herbal/avenae-fructus. For more information about treatment with oat grain medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.