



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Herbal medicine: summary for the public

Willow bark

Salix [various species including *S. purpurea* L., *S. daphnoides* Vill., *S. fragilis* L.], cortex

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

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

What is willow bark?

Willow bark is the common name for the dried bark of various species of the plant *Salix*, including *S. purpurea* L., *S. daphnoides* Vill. and *S. fragilis* L.

The HMPC conclusions only cover willow bark preparations which are obtained by comminuting (reducing into tiny pieces) or powdering the bark and as dry or liquid extracts. Extracts are obtained by putting the plant material in a solvent (such as ethanol or water) to dissolve compounds and form a liquid extract. The solvent is then evaporated to obtain a dry extract.

Herbal medicines containing these willow bark preparations are usually available as herbal tea to be drunk and in solid or liquid forms to be taken by mouth.

Willow bark 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 willow bark prepared as a dry extract can be used for short-term treatment of lower back pain.



The HMPC also concluded that, on the basis of its long-standing use, willow bark preparations can be used for relief of minor joint pain, relief of fever linked with the common cold and for headaches. Willow bark medicines should only be used in adults. They should not be taken for longer than 4 weeks for back or joint pain. If symptoms worsen or last longer than 3 days whilst taking the medicine for fever or 1 day for headache, a doctor or a qualified healthcare practitioner should be consulted. Detailed instructions on how to take willow bark medicines and who can use them can be found in the package leaflet that comes with the medicine.

How does willow bark work as a medicine?

One of the components of willow bark, salicin, is known to have effects on inflammation, fever and pain. Salicin is converted into salicylic acid in the body. It may work similarly to aspirin (which is structurally related to salicylic acid) by blocking enzymes called cyclo-oxygenases which are involved in inflammation and pain.

However, the amount of salicylic acid produced from salicin is small and the effects of the medicine may be due to its other components.

What evidence supports the use of willow bark medicines?

The HMPC conclusions on the use of these willow bark medicines for lower back pain are based on their 'well-established use'. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered a number of clinical studies that showed that willow bark was more effective than placebo (a dummy treatment) at reducing lower back pain.

The HMPC conclusions on the use of these willow bark medicines for relief of minor joint pain, relief of fever linked with the common cold and for headaches 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 willow bark medicines for joint pain and headache. Although a possible effect in reducing joint pain was observed, there were shortcomings in the studies such as small numbers of patients and short duration. Therefore, the HMPC conclusions on the use of these medicines for relief of minor joint pain and headache 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 willow bark medicines?

Side effects with willow bark medicines include allergic reactions, such as rash, exanthema (widespread rash), itching, and asthma, and stomach and gut symptoms such as nausea, vomiting, abdominal (belly) pain, diarrhoea and heartburn. The frequency is not known.

Willow bark medicines must not be taken if patients are hypersensitive (allergic) to salicylates (such as aspirin) or other anti-inflammatory medicines known as NSAIDs (non-steroidal anti-inflammatory drugs). They must also not be taken by people with asthma due to salicylate sensitivity, active stomach ulcers, severe liver or kidney dysfunction, clotting disorders and glucose-6-phosphate dehydrogenase deficiency (a genetic condition that can cause the destruction of red blood cells).

Women in the third trimester of pregnancy, children and adolescents must not take willow bark medicines.

Further information on the risks associated with these willow bark 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: ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use.

How are willow bark medicines approved in the EU?

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

Other information about willow bark medicines

Further information on the HMPC assessment of willow bark medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: ema.europa.eu/Find_medicine/Herbal_medicines_for_human_use. For more information about treatment with willow bark medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.