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Committee on Herbal Medicinal Products (HMPC)

Assessment Report Summary for the Public (ARSP)

Holy thistle (St. Benedict's thistle)

Cnicus benedictus L., herba

Other names

BG (bulgarski): Бенедиктински трън	LT (lietuvių kalba): Karčiųjų šventadagių žolė
CS (čeština): benediktová nať	LV (latviešu valoda): Laimes dzelkšņa laksts
DA (dansk): Benediktinertidse	MT (Malti): xewk
DE (Deutsch): Benediktenkraut	NL (Nederlands): gezegende distel
EL (elliniká): κνίκου ιεράκανθα (βενέδικτου) πόα	PL (polski): ziele drapacza
EN (English): Holy thistle (St. Benedict's thistle)	PT (português): cardo-santo
ES (español): cardo santo, sumidad de	RO (română): iarba de schinel
ET (eesti keel):	SK (slovenčina): vňať benediktu lekárskeho
FI (suomi): karvaskaunokki, verso	SL (slovenščina): zel benediktinke
FR (français): Charbon-béni (partie aérienne de)	SV (svenska): kardbenedikt, ört
HR (hrvatski): zelen blaženog čkalja	IS (íslenska):
HU (magyar): benedekfű virágos leveles hajtás	NO (norsk): Benediktinertistel
IT (italiano): Cardo benedetto parti aeree	



Introduction

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of Holy thistle (St. Benedict's thistle) above-ground parts. It summarises the Committee's recommendations on the use of St. Benedict's thistle above-ground parts.

The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing Holy thistle (St. Benedict's thistle) above-ground parts. When a Member State authorises a medicine containing Holy thistle (St. Benedict's thistle) above-ground parts, detailed instructions on how to take it will be available in the package leaflet that comes with medicine.

The information in this summary report concerns herbal medicinal products containing Holy thistle (St. Benedict's thistle) above-ground parts which are only authorised when they comply with the strict pharmaceutical quality and other requirements for herbal medicinal products. They are approved by the competent authorities to be placed on the market as medicinal products. Other products, like food, food supplements, cosmetic products or medical devices do not follow the same criteria and regulatory requirements as medicinal products and are excluded from this summary.

What is Holy thistle (St. Benedict's thistle) above-ground parts what do Holy thistle (St. Benedict's thistle) herbal medicines contain?

Holy thistle (St. Benedict's thistle) is the common name for the above-ground parts of the plant *Cnicus benedictus* L.

Medicinal products with St. Benedict's thistle contain the comminuted (reduced into tiny pieces), the powdered and liquid extract or tincture of the dried above-ground part of the plant. Liquid extracts and tinctures are obtained by putting the plant material in a solvent (like ethanol) to dissolve compounds and form a liquid extract or a tincture.

Herbal medicines containing Holy thistle (St. Benedict's thistle) above-ground part preparations are usually available as herbal tea to be drunk, and in liquid or solid dosage forms to be taken by mouth.

What are the medicinal uses of Holy thistle (St. Benedict's thistle) above-ground parts?

Holy thistle (St. Benedict's thistle) above-ground parts preparations have traditional use for the **temporary loss of appetite** and for the **symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract**. Traditional medicinal use means that the use in the specified

indication is exclusively based upon long-standing medicinal use and not based on results from clinical studies.

When is it not recommended to use Holy thistle (St. Benedict's thistle) above-ground parts?

You can find detailed instructions on how to take Holy thistle (St. Benedict's thistle) above-ground parts medicines and who can use them in the package leaflet that comes with the medicine.

Do not use Holy thistle (St. Benedict's thistle) above-ground parts:

- for children and adolescents under **18 years** of age.
- if you are **pregnant or breast feed** your child.
- if you are **allergic** to St. Benedict's thistle.

Consult a doctor or a pharmacist if your symptoms persist longer than **2 weeks** during the use of the medicinal product.

What you need to know before taking Holy thistle (St. Benedict's thistle) above-ground parts with other medicines?

No interactions with other medicines have been described in the literature at the time of assessment when using Holy thistle (St. Benedict's thistle) above-ground parts with other medicines.

What are the risks associated with Holy thistle (St. Benedict's thistle) above-ground parts medicines?

You may experience some side effects with Holy thistle (St. Benedict's thistle) above-ground parts medicines.

You may get **allergic** reactions.

The frequency of these undesirable effects is not known.

How does Holy thistle (St. Benedict's thistle) above-ground parts work as a medicine?

The HMPC conclusions on the use of these Holy thistle (St. Benedict's thistle) above-ground parts medicines for the **symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract** and for the **temporary loss of appetite** 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).

How are herbal medicines containing Holy thistle (St. Benedict's thistle) above-ground parts approved in the EU?

Any applications for the licensing of medicines containing Holy thistle (St. Benedict's thistle) above-ground parts have to be submitted to the national authorities responsible for medicinal products. Before approval, the national authorities assess the quality, safety and efficacy of the herbal medicine. The HMPC conclusions are taken into account when evaluating applications for the licensing of herbal medicines.

Information on approved Holy thistle (St. Benedict's thistle) above-ground parts medicines in EU Member States may be obtained from the relevant national authorities.

Further information

Further information on the HMPC scientific assessment of Holy thistle (St. Benedict's thistle) above-ground parts medicines, including details of the Committee's conclusions, can be found under the tab 'Documents' on the Agency's website: [Cnici benedicti herba - herbal medicinal product | European Medicines Agency \(EMA\)](#).