

Data sheet - NATURAL mouthwash

OralSed[®]

COMPOSITION AND PHARMACEUTICAL FORM



OralSed is a mouthwash to be used orally.

The active ingredient is a phytocomplex from the *Uncaria Tomentosa* bark dry extract, titrated at 3% in alkaloids derived from oxindole.

It also contains: water; glycerol; potassium sorbate; potassium benzoate; hydroxyl cellulose; croscarmellose sodium; sucralose; mint flavour.

PROPERTIES

Anti-inflammatory, anti-septic, immunomodulating and soothing effect on the oral mucosa.

This anti-inflammatory effect is due to action of alkaloids derived from oxindole and, minimally, from sterols in the plant.

Alkaloids stimulate macrophages, leukocytes, natural killer cells and the production of anti-inflammatory IL-1 and IL-6 cytokines. In addition to that, alkaloids stimulate the production of anti-bacterial, anti-viral and anti-fungal NO (nitric oxide).

Glycosides of quinovic acid have shown an anti-oxidant effect with free radical scavenger action and with an increase in mitochondrial SODs.

INDICATIONS

Adjuvant for the prevention and the treatment of:

- Irritation and inflammation of the oral mucosa (mucositis)
- Acute and relapsing gingivitis and periodontitis
- Post-operative stomatological treatment
- Stomatitis, pharyngitis
- Gum sensitivity
- Diffuse canker sores and small mouth lesions
- Herpes labialis prevention
- Severe mucositis in patients undergoing chemotherapy or local radiotherapy

USE

Intensive treatment: 10 ml of undiluted product, 2-4 times a day, according to your dentist's advice.

Maintenance treatment - 10 ml of product diluted in a little quantity of water (10 ml) at least twice a day: mornings and evenings, for periods of at least 30 days. The product is to be kept on using in the evenings as prevention for a healthy oral hygiene and it can be diluted in water.

CONTRAINDICATIONS

The product is not to be used by patients with known hypersensitivity and/or allergies to the components of the mouthwash.

SIDE EFFECTS

The medical literature does not provide data which could prove possible side or adverse effects to Uncaria extracts for topical or internal use.

WARNINGS AND STORAGE

There are no studies or evidence that do not recommend the use of this product during pregnancy. No interaction with drugs or herbs has been observed.

To be stored in a cool and dry place away from direct light.

FOCUS : UNCARIA TOMENTOSA

It is a climbing shrub, belonging to the family of Rubiaceae, and it can reach 20 meters in height thanks to its square-shaped woody stem with 2 cm-long thorns; the oval-shaped hairy leaves are bright green and can reach 20 cm in length. There are three *Uncaria* varieties: *tomentosa*, *aculeata*, *guaianensis*. The most studied one is *Uncaria tomentosa*, but more recently also the other two varieties have drawn the attention of researchers.

The name *Uncaria* (called 'cat's claw') comes from the Latin term 'uncus', meaning 'curved, hook-like, hooked' due to its curved hook-shaped thorns. The word 'tomentosa' is due to the lanugo covering the leaves. It has been used for 2000 years in traditional medicine to treat asthma, rheumatism, skin and gastric ulcers, and infections. In Italy, the first laboratory studies have been carried out since 1988.

The bark, collected during spring before flowering, is used. The most used galenic preparations are bark decoction, alcoholic extraction from the dried bark and dry extract with alkaloid titration not lower than 3%.

ACTIVE INGREDIENTS, MECHANISM OF ACTION AND PHARMACOLOGICAL PROPERTIES

The main components of *Uncaria* are: Alkaloids derived from oxindole (mitraphylline, pteropodine).

- Alkaloids derived from oxindole have immunostimulating, anti-inflammatory, and anti-oxidant effects, thus stimulating the nitric oxide (NO) synthesis. Oxindole derivatives influence the immune system, thus activating macrophages, leukocytes, NK cells and the production of anti-inflammatory IL-1 and IL-6 cytokines.

- Anti-inflammatory sterols (beta-sitosterol, Stigmasterol, campesterol)
- Glycosides of quinovic acid with anti-viral properties
- Anti-oxidant polyhydroxylated triterpenes
- Nicotinic acid

Anti-inflammatory and immunomodulating effect

The aqueous extract of the plant has shown anti-inflammatory effects towards carrageenan-induced oedema in the foot of a mouse. In addition to that, injections of plant extracts have shown inhibitory effect on the prostaglandin-synthetase in rabbit microsomes.

Oxindole derivatives have shown to enhance phagocytic activity in lymphocytes, while tetracyclic alkaloids antagonizes said activity.

In animal models, Uncaria extracts have shown to increase the lymphocyte proliferation, to enhance the peripheral white blood cell count and to promote the recovery from chemotherapy-induced leukopenia.

Anti-oxidant effect

Plant extracts have shown to have anti-oxidant effects through an increase in superoxide dismutase in mitochondrial fractions of the cerebral cortex. In addition to that, an aqueous extract of Uncaria has shown a strong scavenging action, in vitro, against superoxide.

CLINICAL RESEARCH

Multiple double-blind clinical studies have shown significant improvements in patients with Herpes Simplex and HIV viral infections. Clinical studies have demonstrated effectiveness for chronic rheumatism and for stomatitis.

INDICATIONS

Acute and chronic inflammation
Immunodeficiency situations
Viral diseases

TOXICITY

The LD (lethal dose) in rats is 8gr./kg. No toxicity has been reported

CONTRAINDICATIONS

Plant Allergy

Clinical studies on Uncaria extracts for stomatitis and oral viral forms

- Uncaria tomentosa Gel against Denture Stomatitis: Clinical Report.
- Tay LY, Dos Santos FA, Jorge JH.J Prosthodont. 2015 Oct;24(7):594-597. doi: 10.1111/jopr.12248. Epub 2015 Feb 9.PMID: 25675972
- Plant metabolites. Structure and in vitro antiviral activity of quinovic acid glycosides from Uncaria tomentosa and Guettarda platypoda.
- Aquino R, De Simone F, Pizza C, Conti C, Stein ML.J Nat Prod. 1989 Jul-Aug;52(4):679-85. doi: 10.1021/np50064a002.PMID: 2553871
- Evaluation of different treatment methods against denture stomatitis: a randomized clinical study.
- Tay LY, Jorge JH, Herrera DR, Campanha NH, Gomes BP, Andre Dos Santos F.Oral Surg Oral Med Oral Pathol Oral Radiol. 2014 Jul;118(1):72-7. doi: 10.1016/j.oooo.2014.03.017. Epub 2014 Apr 5.PMID: 24908596
Clinical Trial.

An observational study carried out by Prof. Giacomo Bruzzesi on 54 patients (28 females and 26 males) with aphthous stomatitis being treated with Uncaria-based mouthwash vs. 55 patients (with canker sores as well, but treated with a chlorhexidine-based product) has shown a clear improvement within three days in the first group treated with Uncaria as compared with the 10 days of the untreated control group. A second group of 70 patients with canker sores and/or herpes being treated with two daily applications, has shown a clear reduction in healing time (of at least 7 days).



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B&B DENTAL
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