Strathmann Hox alpha®

1. NAME OF THE MEDICINAL PRODUCT

Hox alpha®
Hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Nettle leaf dry extract (19 – 33 : 1);
Extraction agent: 2-propanol 95 % (V/V)
145 mg/hard capsule

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard
Colour: green

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

For the supportive treatment of rheumatic complaints.

4.2 Posology and method of administration

Usual dose for adults and adolescents aged 12 years and older:
1 hard capsule, 3 times daily

Hox alpha hard capsules should be taken with sufficient liquid, preferably water, after meals.

In principle, the duration of use is not limited, but rather dependent on the nature, severity and course of the disease. In the package leaflet, the patient is advised that the duration of use should be determined by the physician and that the information in sections 4.4 "Precautions and warnings" and 4.8 "Undesirable effects" must be observed.

4.3 Contraindications

- Hypersensitivity to nettles or to any of the excipients of Hox alpha listed in section 6.1.
- Disorders where reduced fluid intake is indicated (e. g. severe heart or kidney disease).

4.4 Special warnings and precautions for use

During concomitant administration of Hox alpha, the efficacy of coumarin-type anticoagulants may be attenuated. In patients taking such medicinal products, repeated monitoring of blood clotting parameters (INR, prothrombin time) should be undertaken during and approximately 2 weeks after the patient has stopped taking Hox alpha (see section 4.5 Interaction).

In the package leaflet, the patient is advised that a physician must be consulted in the event of acute rheumatic complaints, accompanied by such symptoms as joint redness, swelling or overheating, or if complaints persist.

Patients with diabetes taking Hox alpha should undergo repeated blood sugar monitoring (see section 4.8 Undesirable effects).

Children

There is insufficient information on the use of this medicinal product in children under 12 years. It must therefore not be used in children under 12 years.

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i. e., essentially "sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

Antidiabetic agents

Interaction between Hox alpha and antidiabetic agents cannot be excluded.

Anticoagulants/vitamin K antagonists

Hox alpha contains vitamin K in small amounts. In patients receiving concomitant treatment with a vitamin K antagonist (phenprocoumon: trade name, e. g. Marcumar®, Marcuphen®, Falithrom® or warfarin: trade name Coumadin®) to affect blood clotting, the efficacy of these medicinal products may be attenuated. Therefore, repeated monitoring of blood clotting parameters (INR, prothrombin time) is necessary during use and for up to 2 weeks after discontinuation of Hox alpha.

4.6 Pregnancy and lactation

To date, the use of nettle herb as a foodstuff has shown no evidence of any risks during pregnancy and breastfeeding. However, there are insufficient studies available on the use of Hox alpha in pregnancy and breastfeeding. Hox alpha is therefore not recommended for use during pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machines

Hox alpha has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The following frequencies are used for evaluating adverse reactions:

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(< 1/10,000)
Not known	(cannot be estimated from the available data).

Possible side effects

Uncommon: hypersensitivity reactions of the skin (e. g. in the form of pruritus, exanthema, urticaria) may occur.
Uncommon: gastrointestinal complaints such as nausea, diarrhoea and vomiting may occur.
Very rare: In patients with diabetes mellitus, there have been reports of an increase in blood sugar with the administration of nettle leaf or nettle herb preparations, which regressed upon discontinuation of the medicinal product.
Note: Uncommon: increased urinary urgency may occur.

At the first sign of a hypersensitivity reaction, the patient must discontinue taking Hox alpha.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website www.bfarm.de.

4.9 Overdose

To date, there have been no reported cases with nettle leaf preparations. The symptoms described under Undesirable effects may occur in a more intense form. In the package leaflet, the patient is instructed to notify a doctor if they have taken excessive amounts of Hox alpha.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Herbal medicinal product for muscle and joint pain
ATC code: M09AP

The efficacy of nettle leaf preparations is documented by the preparation monograph for *Urticae herba* (nettle herb), *Urticae folium* (nettle leaves), published in the German Federal Gazette No. 76 of 23/04/1987.

According to phytotherapeutic principles, the entire drug is regarded as an active substance.

Toxicological properties
Acute, chronic and subchronic toxicity

Based on animal experiments, Hox alpha is largely non-toxic (LD_{50} in mice and rats more than 5 g/kg BW, oral administration). It produces no toxic effects at doses up to 2.7 g/kg BW over 4 weeks.

Toxicity to reproduction

No reproductive toxicity studies are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quinolone yellow (E 104)
Gelatin
Purified water
Colloidal anhydrous silica
Hypromellose
Indigo carmine (E 132)
Macrogol 4000
Magnesium stearate (Ph. Eur.) [vegetable]
Microcrystalline cellulose
Sodium dodecyl sulphate
Povidone
Hydrated silica
Talc
Titanium dioxide (E 171)

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store in the original package in order to protect from light and moisture.
- Do not store above 25 °C.

6.5 Nature and contents of container

Blister strips in folded boxes
Packs with 50 N2, 60, 100 N3, 120, 200 and 220 hard capsules
Hospital packs with 500 (10 × 50) and 2500 (50 × 50) hard capsules
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

6873946.00.00

9. DATE OF RENEWAL OF THE AUTHORISATION

18/06/2003

10. DATE OF REVISION OF THE TEXT

October 2022

11. GENERAL CLASSIFICATION FOR SUPPLY

Available from pharmacies only