NUTRIHYL®

Hyaluronic acid of biotechnological origin for the nutritional industry

CHEMICAL NAME

poly (sodium-β-D-glucuronate-[1-3]-β-N-acetyl-D-glucosamine-[1-4])

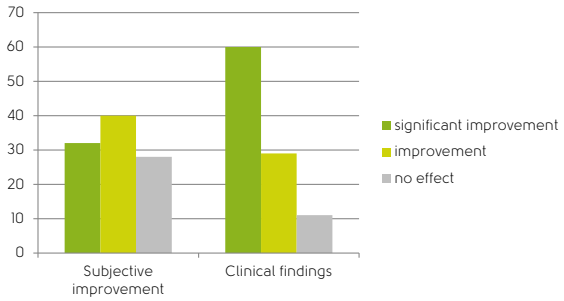
Sodium hyaluronate (hyaluronan, sodium salt of hyaluronic acid) is a non-sulphated glycosaminoglycan, a naturally occuring polysaccharide.

EFFICACY DATA

The influence of Nutrihyl® and chondroitin sulphate combination on joints after knee surgery

27 patients were studied in the university orthopaedic clinic in Prague. More than 70 percent of patients subjectively found significant improvement or improvement in swelling and joint painfulness and movement capability.

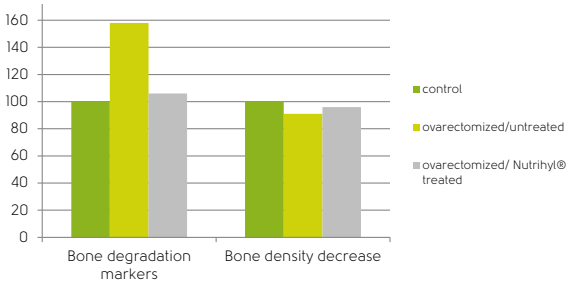
Clinical findings were even better, 60 and 28 percent of patients showed significant improvement or improvement in evaluated parameters.



The influence of Nutrihyl® on experimentally caused osteoporosis

Osteoporosis was experimentally induced in laboratory female rats by ovarectomy. The experiment with ovarectomized rats simulates women after menopause. We have observed that Nutrihyl®, given per orally, with different molecular weight and at different dosages has positive effect on parameters characterizing bone degradation and bone density.

Results showed lower content of bone degradation markers (pyridinoline and deoxypyridinoline) in urine and lower bone density decrease in group treated with Nutrihyl®.



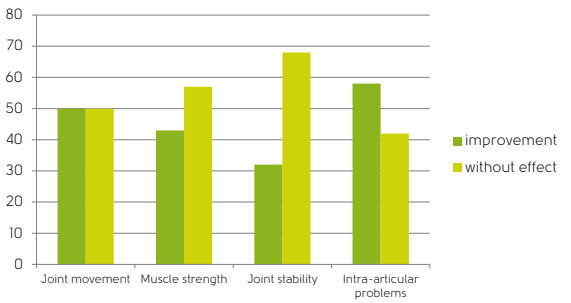
Distribution of Nutrihyl® on experimental adjuvant arthritis

We found that Nutrihyl® with molecular weight of more than 1 MDa significantly reduces swelling of the hind leg point after arthritis development, experimentally caused by the suspension of thermally killed Mycobacterium in incomplete Freud adjuvants in rats (14^{th} day $p < 0.05$, 21^{st} and 28^{th} day $p < 0.001$). It is active at a very low concentration (0.1 mg/kg of the body mass is sufficient).

The influence of Nutrihyl® on the state of knee joint on ice-hockey players

The study made in the Musculosceletal Institute in Prague with 24 ice-hockey players of the premier league was focused on joint movement, muscle strength, joint stability and intra-articular problems. The group was treated for 90 days during the sport season, the disposition of the sportsmen was evaluated before and after the treatment by a doctor.

The overall results showed improvement between 30-60 percent in all evaluated parameters.



SPECIFICATION: **Nutrihyl®**

Origin	biotechnological processing
Appearance	white to yellowish powder or granules
Appearance of 1% aqueous solution	clear to slightly opalescent solution
Smell	slight, characteristic
pH of 0.5% aqueous solutions	5.0 – 8.0
Loss on drying (%)	≤ 10.0
Ash (%)*	≤ 10.0
Uronic acids (%)*	≥ 43.5
Sodium hyaluronate (%)*	≥ 90.0
Protein content (%)*	≤ 1.0
Heavy metals (ppm)	< 20
Arsenic (ppm)	< 2
Total microbial count (CFU/g)	≤ 100
Test for specific microorganisms (Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Salmonella sp., Enterobacteriaceae)	absent
Molecular weight (MDa)	≥ 1.0
Residual isopropanol (%)	≤ 0.1

* calc. on dry basis

Application forms and daily dosage

RECOMMENDED APPLICATION FORMS

- syrup with neutral pH (important from the stability point of view)
- gel
- capsules or tablets
- health bars

RECOMMENDED DAILY DOSAGE (mg)

	HUMAN	HORSE	DOG
OSTEOCHONDRAL DEFECTS	20 – 90	50 – 250	30 – 150
OSTEOPOROSIS	20 – 90	50 – 250	30 – 150
SKIN AND HAIR SUPPORT	35 – 70		

Storage conditions

- Storage: store in originally sealed packaging in a cool and dry place
- Shelf-life: 36 months

Solubility

- soluble in water. Sodium hyaluronate with molecular weight higher than 1 MDa forms a viscous solution at the concentration of 1%, whilst 2% sodium hyaluronate forms gel. Due to the presence of glucuronic acid in the structure, hyaluronate forms salts with different cations. Salts with simple cations such as sodium, potassium calcium, magnesium ets. are fully soluble in water in contrast to salts formed with polymeric or hydrophobic cations.
- limited solubility in alcohol-water mixture. Soluble in the mixture if the concentration of alcohol is below 40%.
- insoluble in non-polar solvents

Compatibility and processing of solutions

- sensitive to heat. Heating to 90 °C for 45 min. can lead to the molecular weight decrease up to 20%.
- sensitive to low and high pH. Extreme values lead to molecular weight decrease, which is further enhanced by product heating.
- incompatible with cationic substances.

Literature

Thierry, B., Winnik, F.M., Merhi, Y., Silver, J. And Tabrizian, M. Radionuclides-hyaluronan-conjugate thomboresistant coating to prevent in-stent restenosis, Biomaterials (2004), 25, 3895-3905

Stancikova, M., Svik, K., Istok, R. and Velebny,V. The effects of hyaluronan on bone resorption and bone mineral density in rat model of estrogen deficiency-induced osteopenia, Int J Tissue React. (2004), 26(1-2):9-16.

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Version: P-01/2017