



SUPLASYN[®] m.d.

Sterile sodium
hyaluronate solution
Supplement for small synovial joints

Non Avian Derived (NAD)
Non Heat Degraded (NHD)
Sodium hyaluronate



BIONICHE
PHARMA GROUP LIMITED
www.suplasyn.com

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Suplasyn m.d. is superior to corticosteroids for the treatment of rhizarthrosis¹

Prospective randomized controlled study.
51 patients randomized to receive Suplasyn 4 x 0.5 ml (5 mg) at weekly intervals or 1 injection dexamethasone 1ml (4 mg).
Evaluations at baseline, 1 month and 6 months.
Assessment of VAS pain, patient global condition and safety.

Conclusions

- ▶ **Suplasyn shows comparable efficacy to dexamethasone 1 month after treatment.**
- ▶ **The efficacy of Suplasyn is maintained for at least 6 months, as opposed to that observed for dexamethasone.**
- ▶ **Suplasyn is safe for the treatment of symptoms of osteoarthritis.**

VAS PAIN SCORE (MEAN)

Time Point	Suplasyn (Mean)	dexamethasone (Mean)
Baseline	~58	~58
1 month	~29	~36
6 months	~29	~48

Summary of p values at	Suplasyn (n=24)	Dexamethasone (n=27)	Between arms
Baseline			0.73
1 month (vs baseline)	< 0.0001	< 0.0001	0.40
6 months (vs 1 month)	0.91	< 0.0001	< 0.0001

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Suplasyn m.d. is effective in the treatment of Golfer's toe²

Single centre, single arm, open-label trial.
47 golfers with OA of the 1st MTP joint.
8 x 1 ml Suplasyn at weekly intervals.
Assessments at baseline, 9 & 16 weeks, follow up (28-76 weeks).

Conclusions

- ▶ **Significant reduction from baseline pain at rest and tip toe walking at all assessment times.**
- ▶ **High global patient satisfaction.**
- ▶ **No local or systemic adverse event.**

EFFICACY MEASURES

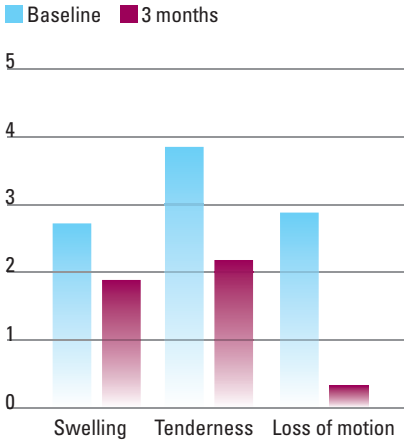
Time Point	Rest pain (mm)	Tip toe walking pain (mm)	ROM (degrees)
Baseline	~40	~68	~8
9 weeks	~29*	~39*	~24*
16 weeks	~29*	~31*	~24*
Follow up	~23*	~59*	~27*

* P < 0.05

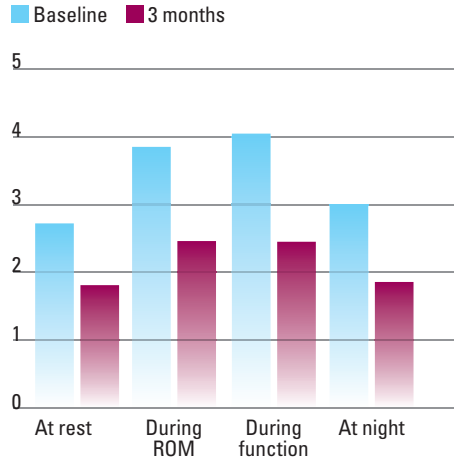
The benefits of Suplasyn m.d. are confirmed in real life practice³

Longitudinal, prospective, observational, multinational survey on IA injection of Suplasyn for hand OA in clinical practice settings. 84 patients received 3 x 1ml Suplasyn. Assessments at baseline and month 3 (82 patients): joint condition, pain, patient & physician impression of change.

JOINT ASSESSMENT WEIGHTED AVERAGES

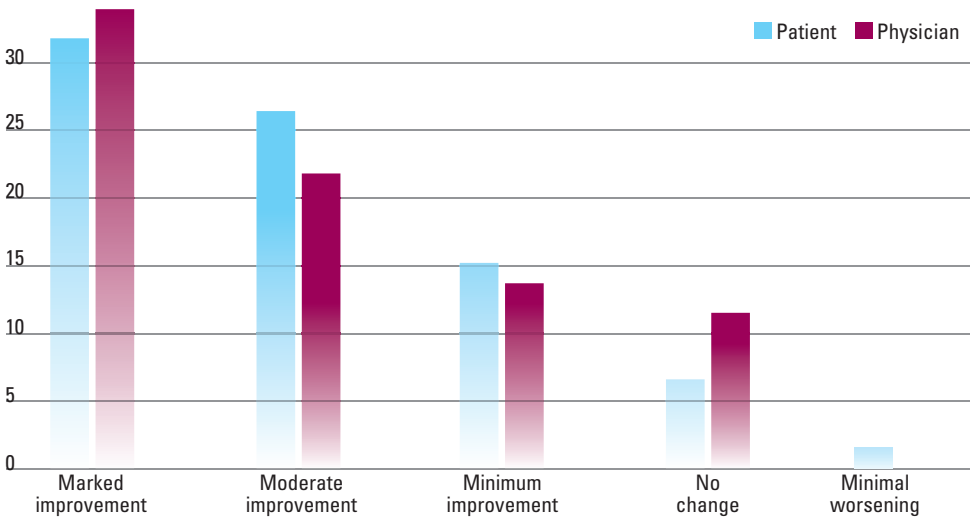


PAIN - WEIGHTED AVERAGES



GLOBAL IMPRESSION OF CHANGE

Patients



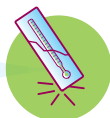
Conclusions

- ▶ Intraarticular injections of Suplasyn provided significant improvement in joint function and pain relief in hand OA patients.
- ▶ There was no local or systemic treatment related adverse event reported.



▶ **Suplasyn m.d. is Non-Avian Derived, produced by bio-fermentation**

- No risk of cross-species contamination
- No risk of allergic reaction to avian proteins



▶ **Suplasyn m.d. is Non Heat Degraded, sterilized by sterile filtration**

- No risk of heat degradation of the Na-HA molecule
- Limited risk of low molecular weight fractions



▶ **The average Molecular Weight of Suplasyn m.d. (500-1'000 kDa) is carefully selected and monitored to**

- Optimize primary (mechanical) and ancillary (biological) effects of Na-HA therapy (including stimulation of endogenous production of hyaluronan)^{4,5}
- Ensure that it is comfortable to inject, easy on the joint, well tolerated and safe.



▶ **Suplasyn m.d. was specifically designed for small joints.**

- It is presented in pre-filled 0.7 ml syringes containing 7 mg of Na-HA (1%),
- The volume of injection is well adapted, ensuring appropriate dosage.
- The syringe itself (1.2 ml, short plunger) gives the physician greater comfort, control and maneuverability for the injection.

References

- 1 - Local treatment of Rhizarthrosis: Suplasyn versus dexamethasone, a Prospective Randomized Controlled Study R.Cabezas, A.Rodriguez de la Serna. (Poster P237) EULAR, Portugal 2003
2. Intraarticular Hyaluronic Acid treatment for Golfer's toe. R.Petrella, A Cogliano - The Physician and Sports Medicine, Vol. 32, No 7, July 2004
- 3 - Real Practice Data registry in Hand Osteoarthritis. Bioniche Pharma Group, data on file
- 4 - Potential Mechanism of Action of Intra-articular Hyaluronan Therapy in Osteoarthritis: Are the Effects Molecular Weight dependent ? P.Ghosh & D.Guidolin. Seminars in Arthritis and Rheumatism 2002; 32 (1) :10-37.
- 5 - Hyaluronans: Is clinical effectiveness dependant on molecular weight ? P.C Vitanzo et al. Review Paper. The American Journal of Orthopedics. September 2006.

Guidelines

EULAR evidence based recommendations for the management of hand osteoarthritis: Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCI-STI).

Zhang et al. Ann.Rheum.Dis. 2007; 66:377-388

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