

For more information



www.suplasyn.com

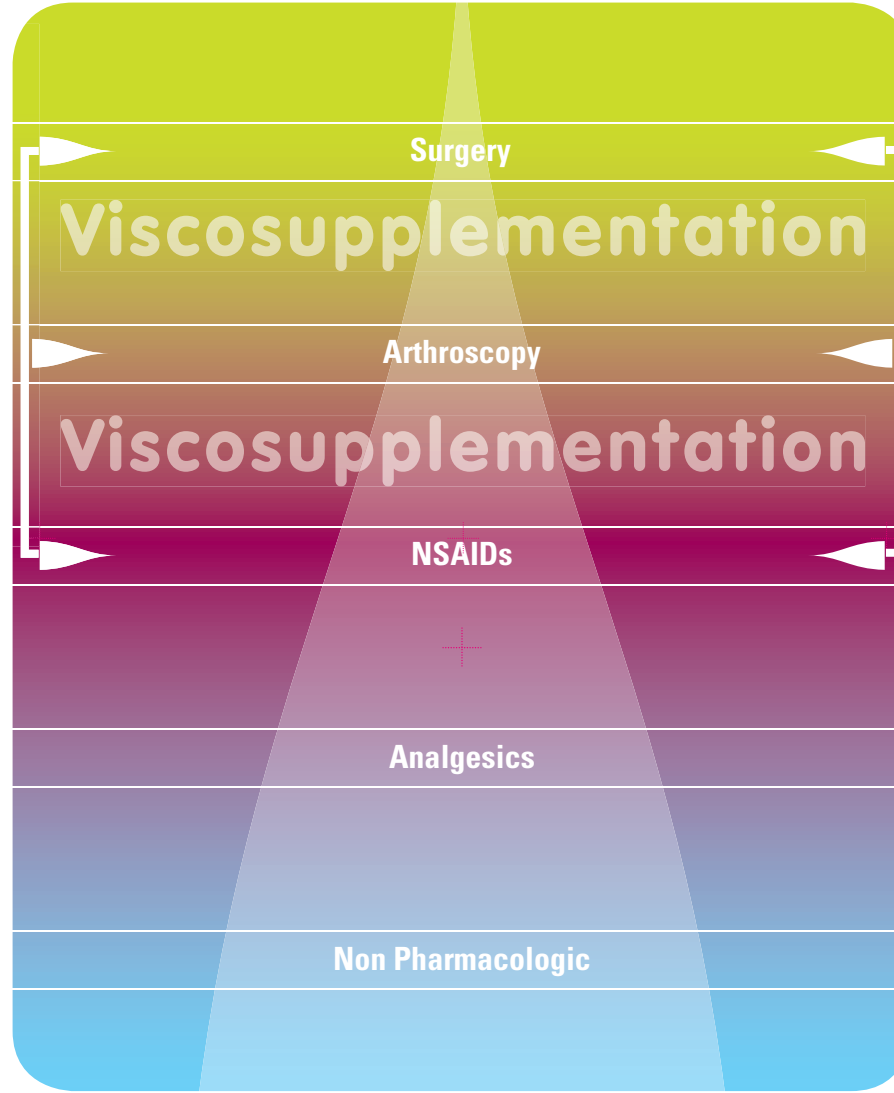
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Important note: Informations herein are given as guidelines only. In no way do they engage the responsibility of Bioniche Pharma Group. Standard operating procedures and local regulations may vary and should prevail. Consult individual products instruction leaflets.

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Treatment guidelines for osteoarthritis of the knee



Na-HA INJECTIONS : PATIENT PROFILE

- Accurate diagnosis of OA
- Mild to moderate radiological grade (1-3)
- Symptomatic – pain (uni-compartmental)
- Insufficient response to analgesics
- Insufficient response, intolerance or contra-indications to NSAIDs
- No active inflammation, symptom flare or significant joint effusion
- Consenting to IA injection

Intraarticular injection of Na-HA for the treatment of OA is validated by ACR guidelines 2000 / EULAR 2003 recommendations / OARSI expert consensus guidelines 2008

Guidelines to IA treatment of osteoarthritis

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- Use reliable product
 - Follow anatomical landmarks
 - Adapt injection volume and needle size
 - Bring product to room temperature
 - Ensure meticulous aseptic technique
 - Aspirate synovial fluid
 - Do not inject intra-vascularly
 - Inject with slow steady pressure
 - Apply pressure over site after needle withdrawal
 - Keep patient under observation 15 minutes
- ## THE PROCEDURE
- Consider treatment as part of overall disease management
 - Rest 24-48 hours after injection
 - Avoid strenuous activity over full course of treatment
 - In case of post injection pain or inflammation: use RICE, NSAIDs. Come back for consultation if symptoms are severe
 - Ensure meticulous aseptic technique
 - Aspirate synovial fluid
 - Do not inject intra-vascularly
 - Inject with slow steady pressure
 - Apply pressure over site after needle withdrawal
 - Keep patient under observation 15 minutes

THE MANAGEMENT

- Right indication
- No contra-indication
- Patient information and consent

THE PATIENT

The golden rules

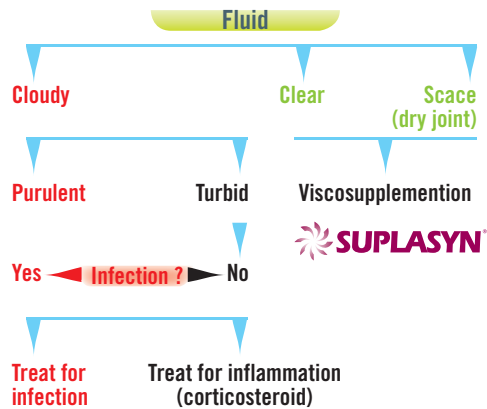
Guidelines to IA injections

FLUID ASPIRATION

Aspiration is recommended before any IA injection to:

- Make sure the needle is well in place and not in a blood vessel
- Check the nature of the fluid
- Remove fluid to avoid dilution of injected product (note: dry joints are frequent in OA)

Algorithm based on fluid aspiration



AN INJECTION FLOW CHART

Pre-injection steps

- Bring injectable product at room temperature
- Prepare 2x3cc or 1x10cc syringes for aspiration before injection
- Position joint to stretch capsule and separate joint ends
- Ensure meticulous aseptic technique
- Stretch clean skin at injection site, insert needle rapidly
- Draw back on plunger, aspirate

Injection steps

- In case of dry joint and in doubt on position of the needle: inject 1-2cc of saline to verify that it flows easily
- Administer product with slow steady pressure
- Withdraw needle rapidly
- Press on site with cotton wool or gauze sponge with disinfectant

Post-injection steps

- Apply plaster on injection site (except if patient is allergic)
- Keep patient under surveillance for 15 minutes
- Recommend rest for 24-48 hours after injection
- Give advise should inflammation or pain occur in next few days

Rationale

- Correctly place needle
- Avoid blood vessels
- Check joint fluid

- Ensure effective drug deposition
- Minimize bleeding

- Prevent tracking infection or bleeding
- Check for anaphylactic reaction, stress reaction - reassure patient
- RICE. Consultation where appropriate

CONTRA-INDICATIONS

Absolute contra-indication

- Any lesion at injection site (inflammation, infection...)
- Suspicion of infection in the joint
- Suspicion of infection in any organ, febrile patient
- Hypersensitivity to injected substance
- Very unstable joint
- Prosthetic joint
- Reluctant patient

Relative contra-indication

- Anticoagulants
- Bleeding / coagulation disorder
- Immuno-suppression
- Diabetes (especially for injection of corticosteroids)
- Severe anxiety (risk of vagal shock)
- Gut feeling ! When in doubt: don't inject !

Specific contra-indications for Na-HA

- Effusion, active inflammation, symptom flare
- Venous or lymphatic stasis in the leg (for knee OA)
- Response failure to prior injections of Na-HA in the same joint
- Allergy to avian proteins (only for products of Avian origin, does not apply to Suplasyn)
- Pregancy, lactation, children < 18 years (insufficient data)

SAFETY PRECAUTIONS

1. Follow anatomical landmarks

2. Use strict aseptic techniques

- Clean room – no person with active infection should attend the procedure
- Sterile disposable needle
- Single dose syringe
- Clean dry hands, washed with antiseptic soap
- Surgical gloves
- Protective mask (depending on local SOP)
- Thoroughly clean site with antiseptic soap
- For Na-HA avoid quaternary ammonium
- Avoid shaving the injection site
- Sponge area with alcohol (70% isopropyl alcohol)
- Use « no touch » technique – do not guide needle with the finger
- Apply sponge or cotton swab after needle withdrawal

3. Inform the patient

- There is a small risk of introducing infection into the joint (< 1:16'000)
- Self limited inflammation may follow the injection (pain, swelling, heat). The frequency is app. 1-3% injections
- In case of inflammation use RICE (Rest, Ice,

- Compression, Elevation) & analgesics
- If symptoms are severe and / or persist beyond a few days: come back for examination
- Rest 24-48 hours following injection
- Avoid any strenuous activity during the full course of the treatment
- Response to Na-HA therapy is not immediate and may take a few weeks to fully develop

4. Adapt injection volume & needle to joint and patient

Joint	Needle-G	Maximum injection volume (ml)
Shoulder	21	8
Elbow	23-25	4
Wrist	23	2
Finger (thumb)	25	0.75 (1)
Hip	22	10
Knee	21-23	10
Ankle	23	4
Toe	25	1.5

Indicative and not specific for Na-HA. Consult product leaflets
Source: S.Saunders. Injection techniques in Orthopaedic and Sports Medicine (2002 & 2006).

ADVERSE EVENTS AND MANAGEMENT

Adverse events are possible with any IA injection, including saline solution as placebo

With Suplasyn, adverse events :

- Occur in less than 2% of injections (clinical trials : 1.3 – 1.7%)
- Are usually transient (2-4 days) and self limited
- Occur as inflammation of the injected knee, possibly with pain, swelling, effusion, redness, warmth
- May rarely result in severe inflammation and pain requiring further examination and specific measures
- May very rarely result in a systemic reaction (fever, chills, rash/itching, allergy)
- Leave no permanent sequelae
- Do not preclude treatment success

Management of Adverse Events

- RICE – analgesics – possibly NSAIDs
- If case is severe or persistent
- Aspirate/analyze significant effusions (serology, gram-staining, inflammation markers, crystallopathy markers... corroborate with blood sample)
- Consider IA steroid

In case of infection

- Drainage
- Lavage
- Antibiotics as appropriate

Minimizing Adverse Events

- Right indication
- No contra-indication
- Do not inject product that was not stored appropriately
- Avoid simultaneous injection of different products in the same joint
- Strictly aseptic technique
- Patient information
- Rest after injection