

140mm

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PRESENTATION

HYORTH is a sterile, non-pyrogenic, viscoelastic preparation supplied in the volumes of 2.0 mL in disposable glass PFS.

Each ml of 1% Sodium Hyaluronate Sterile Solution contains:

Sodium Hyaluronate	BP	10 mg
Sodium Chloride	USP	8.5 mg
Di-Sodium Hydrogen Phosphate dihydrate	USP	0.28 mg
Monosodium Phosphate monohydrate	USP	0.04 mg
Water for Injection	USP	q.s.

Contains no preservatives.

HYORTH is terminally sterilized and aseptically packaged product.

STORAGE

Store below 30°C. Do not freeze.

Keep out of reach and sight of children.

For intra articular use only.



FOR THE USE OF REGISTERED MEDICAL PRACTITIONER OR HOSPITAL OR A LABORATORY ONLY

HYORTH Injection

Sodium Hyaluronate Sterile Solution
20mg/2ml

PRODUCT INFORMATION

DESCRIPTION

HYORTH is a sterile, non-pyrogenic, transparent viscoelastic preparation of highly purified, non-inflammatory, high molecular weight fraction of Sodium Hyaluronate. **HYORTH** contains 10 mg/mL of Sodium Hyaluronate dissolved in a physiological Sodium phosphate buffer (pH 7.0-7.5). This polymer consists of repeating disaccharide units of N-acetylglucosamine and Sodium glucuronate linked by β (1-3) and β (1-4) glycosidic bonds.

CHARACTERISTICS

Sodium Hyaluronate is the physiological substance that is widely distributed in the extra cellular matrix of connective tissues. For example, it is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin, and the umbilical cord. Sodium Hyaluronate derived from various human or animal tissues does not differ chemically.

INDICATIONS

HYORTH is indicated for the treatment of pain in Osteoarthritis (OA) of the knee and other synovial joints, in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics.

CONTRAINDICATIONS

HYORTH is contraindicated in patients with known history of hypersensitivity (allergy) to Sodium Hyaluronate preparations, knee joint infections or skin diseases in the area of injection site.

STERILE

Do not reuse

Do not use if pack is damaged.

Manufactured by:

Virchow Biotech Pvt. Ltd.,
Survey No.172 Part, Gagillapur (V), Dandigal-Gandimaisamma (M),
Medchal-Malkajgiri (D), Telangana (State) - 500043, India

Manufactured for:

Virchow Healthcare Private Limited
901, DLH Park, S.V. Road,
Goregaon (W), Mumbai - 400 062, India
www.virchowhealthcare.com

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WARNINGS

1. Do not use concomitantly with disinfectants containing quarternary ammonium compounds for skin preparations, because Sodium Hyaluronate is precipitated in their presence.
2. Do not inject **HYORTH** extra-articularly or into the synovial tissues and capsules. This will generally result in local and systemic adverse events.
3. Intravascular injections of **HYORTH** may lead to systemic adverse events.

PRECAUTIONS

1. The effectiveness of a single treatment cycle of less than 3-5 injections has not been established.
2. The effectiveness and safety of the use of **HYORTH** in joints other than knee have not been established.
3. The safety and effectiveness of the use of **HYORTH** concomitantly with other intra articular injectables have not been established.
4. Strict aseptic administration technique must be followed.
5. The safety and effectiveness of the use of **HYORTH** in severely inflamed knee joints have not been established.
6. The pre filled syringe is intended for single use. Use the contents of the syringe immediately after its packaging is opened. Discard any unused **HYORTH**.
7. Opened or damaged packages of **HYORTH** should not be used. Always store in the original packaging at 30°C.
8. Aspirate synovial effusion if present before each **HYORTH** injection.
9. **HYORTH** should be used with caution when there is evidence of lymphatic or venous stasis in that leg.

USE IN SPECIFIC POPULATIONS

Pregnant women, Nursing mothers and Pediatric age group:
The safety and effectiveness of **HYORTH** have not been established in pregnant women, lactating mothers and children.

ADVERSE EVENTS

Intra articular injection may lead to local side effects like pain, heat sensation, reddening and swelling at the treated joint.

Placing an ice pack on the treated joint for 5 to 10 minutes would reduce the occurrence of such side effects.

DIRECTIONS FOR USE

1. **HYORTH** is administered by intra articular injection. A treatment cycle consists of three to five injections given at weekly intervals. Several joints can be treated simultaneously.
2. Strict aseptic administration technique must be followed. Inject subcutaneous lidocaine or similar local anesthesia prior to injection of **HYORTH**.
3. Aspirate joint effusion before injection of **HYORTH**. Do not use same syringe for removing joint effusion and for injection of **HYORTH**.
4. Take care to remove the tip cap of the syringe and needle aseptically. Inject **HYORTH** into the joint through a 19 G Sterile Needle.
5. The syringe is intended for single use. The contents of the PFS must be used immediately once the container is opened. Before injection, the air bubbles are removed from the injection.
6. Inject the full 2 mL in one knee only. If treatment is bilateral, a separate syringe should be used for each knee.

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