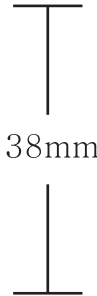


158x220



38mm

For arthritis
High Hyalplus

Sodium Hyaluronate / prefilled



High Hyalplus

【Composition】

Each mL contains:
Sodium hyaluronate 10mg, Sodium chloride 8.5mg, Disodium hydrogen phosphate, Sodium dihydrogen phosphate, and water for injection q.s. to 1mL

【Description】

High Hyalplus is a sterile, transparent viscoelastic fluid containing 10 mg/mL of sodium hyaluronate. Sodium hyaluronate (sodium salt of hyaluronic acid) belongs to a group of very few substances which are identical in all living organisms. It is a natural poly-saccharide that is present throughout the tissues of the body, with particularly high concentrations in the synovial fluid and the skin. High Hyalplus is degraded in the body by the same metabolic pathway as endogenous hyaluronic acid.
The product is for single use only.

【Indications】

For the treatment of pain in osteoarthritis of the knee

【Dosage】

Administer 20mg (2mL) by intra-articular injection in affected knee once weekly for a total of 3 injections.

【Contraindications】

High Hyalplus should not be injected:

- If the patient is known to be sensitive to hyaluronic acid based products,
- If there is a skin disease or infection present at or near the injection site,
- If the knee joint is infected or severely inflamed,

【Precautions】

- Do not inject intravascularly
- Do not inject extra-articularly or into the synovial tissue and capsule. Adverse events, generally in the area of the injection, have occurred following extra-articular injection of High Hyalplus.
- High Hyalplus should not be used if there is a large intra-articular effusion prior to the injection.
- As with any invasive joint procedure, it is recommended that the patient avoids any strenuous activity following the intra-articular injection, and resume full activities within a few days.

- High Hyalplus has not been tested in pregnant women or in children

【Adverse events】

Adverse events involving the injected joint: transient pain and/or, swelling and/or effusion of the injected joint may occur after intra-articular High Hyalplus. In some cases the effusion may be large and can cause pronounced pain; it is important to remove and to analyze the fluid to rule out infection or crystalline arthropathies. These reactions generally abate within a few days. Clinical benefit from the treatment may still be apparent after such reactions. Intra-articular infections did not occur in any of the clinical trials and have been reported only rarely during clinical use of High Hyalplus.

【Administration】

- High Hyalplus should only be injected by an authorized physician or in accordance with local legislation.
- High Hyalplus should be injected using strict aseptic technique, taking particular care when removing the protective seal from the syringe.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- An appropriate needle should be used. The recommended needle size is 22 to 23 G.
- Remove joint effusion, if present, before injecting High Hyalplus. The same needle should be used for both removal of effusion and injection of High Hyalplus.
- Inject into the joint space only.
- The syringe, the needle and any unused material must be discarded after the treatment session.
- If the blister package or syringe is opened or damaged, do not use.
- Do not mix High Hyalplus with other injectable materials.

【How supplied】

High Hyalplus is supplied in a pre-filled glass syringe, packed in a blister pack. The contents of the syringe are sterile and endotoxin-free. Store between +2°C and +25°C. Do not freeze.



Aseptic Sterile



Caution, Consult accompanying Documents



Do not reuse



Manufacturer



Use by



EC Representative



Batch Code



Temperature Limitation



Humedix Co., Ltd.
17, Bio valley 2-ro, Jecheon-si,
Chungcheongbuk-do 390-250, Korea



CLONEW Sylwia Klonowska, Poland
ul. kakowa 2F 77-300 Cztuchow Poland

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