solatum™

Sodium Hyaluronate

solatumfarma

Medical Sodium Hyaluronate Gel
Intra-articular Joint Injection Pre-filled Syringe

Composition

Sodium hyaluronate	20 mg/mL
NaCl	8.5 mg/mL
Na_2HPO_2	0.34mg/mL
NaH_2PO_4	0.14 mg/mL
Water for injection	q.s. to weight

Primary ingredients and performance

Solatum is a clear gel solution, obtained by dissolving sodium hyaluronate or hyaluronic acid (hereinafter as 'HA') in phosphate buffered saline, which is contained in a pre-filled syringe.
Solatum is for a single intra-articular injection. The product is a unique type of linear macromolecular mucopolysaccharide, composing repeating disaccharide units of glucuronic acid and N-acetyl glucosamine. Its chemical formula is $(C_{14}H_{21}NO_{11})_n$. It is supplied in the concentration of HA at 20 mg/mL.

Solatum, is of non-animal origin, with the advantages of high viscoelasticity, lubricity, physical alterability and good biocompatibility. It is a medical polymer extracted and refined by high-tech bio-engineering from streptococcal fermentation metabolites. It is sterile and free from pyrogenicity, allergy, genetic toxicity, or skin irritation. Due to fermentation production of HA, the product has no risk of being a virus carrier.
This product can be used as an orthopaedic agent to improve the joint function. When used in joint cavities, due to its macromolecular characteristics and good viscoelasticity, it stimulates synovium to produce high molecular sodium hyaluronate, which is beneficial for relieving joint pain, increasing mobility, decreasing synovitis and delaying disease progression.

Indications

Solatum is indicated for the treatment of symptoms of osteoarthritis of the knee. By replacing and supplementing the pathological synovial fluid in the osteoarthritic joints, it reduces pain and improves joint function.

Instructions for use

A. To attach needle to syringe

1. Remove the rubber cap. Hold syringe pull rubber cap off the syringe.
2. Insert needle. Hold the syringe body and firmly insert the hub of the needle (select a suitable needle) into the luer-lock at the end of the syringe.
3. Tighten the needle by turning it firmly in a clockwise direction until it is seated in the proper position.

B. Physician instructions

1. As Solatum is administered by intra-articular injection, the injection of Solatum should be performed only by trained physicians.
2. Aseptic injection procedure should be followed.
3. If joint effusion presents, it should be aspirated before performing the injection. The dosage regimen is injecting the product into the affected synovial joint cavity with only one injection.
4. Discard the syringe and needle after the single use.

The dosage regimen is injecting into the affected synovial joint space with only one injection.

Adverse reactions

Mild transient local pain, swelling, arthralgia and joint stiffness at the injections site have been reported after intra-articular injections. These symptoms are generally mild and transient. They usually resolve within 2 to 7 days without medical intervention. If symptoms are persistent, please consult with your doctor.

Precautions

1. Strict aseptic technique must be followed preventing patients from cross-infection:
2. The pre-filled syringe is intended for single use. The contents of the syringe must be used immediately after opening the packaging. Discard any remaining part of Solatum. Secondary use may to lead to some infectious diseases.
3. Do not use if the blister package is in damaged condition, or if any cracks or breakage appears on the pre-filled syringe;
4. Do not use intravenously;
5. Do not inject Solatum into the synovial tissue or capsule;
6. If the joint is infected do not use Solatum intra-articular joint injection;
7. Do not use disinfectants containing quaternary ammonium salts simultaneously for skin preparation, since sodium hyaluronate may precipitate when in contact with this ingredient.

Contraindications

1. Solatum is contraindicated for patients with known hypersensitivity (allergy) to Solatum or any other sodium hyaluronate preparations;
2. Solatum is contraindicated for patients with skin diseases or infection in the area of injection site;
3. Solatum is contraindicated for patients with acute and chronic pyogenic arthritis, synovium and joint tuberculosis, haemorrhagic diseases and haemophilia.

Notes

The container for medical sodium hyaluronate is composed of glass. Please use carefully.
Do not use after expiry date printed on the package. The expiry date refers to the product stored in its original packaging at the temperature between 2°C - 20°C.
Keep out of reach of children.
The safety and effectiveness of Solatum has not been tested on paediatric patients, pregnant or lactating women.

Storage

Store between 2°C and 20°C, do not freeze.
Relative humidity shall be no more than 80%.
Store in a clean, well ventilated condition, and avoid corrosive gas.
Product from light.

Shelf life

2 years.

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Technological Development Zone, Zhejiang, China.
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Protect from light.

Shelf life

2 years.

Specifications

20 mg/ml : 3.0 ml (60 mg/3ml).

Effective Date

June 2019.

8.03.04.378-AO

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