Sodium Hyaluronate

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

Composition
Sodium hyaluronate 20 mg/mL
NaCl 8.5 mg/mL
Na₂HPO₄ 0.34 mg/mL
NaH₂PO₄ 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.
Indication
Indicated for the 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. When injected into joint cavities can help with lubrication and buffering of damaged cartilage, suppression of inflammation and stimulation of production of high molecular weight hyaluronic acid (hyaluronate), which can help with joint pain, increasing mobility, decreasing synovitis and delaying disease progression.

Contraindication
Not suitable for the following patient groups:
- With acute and chronic pyrogenic arthritis, synovium and joint tuberculosis, haemorrhagic disease and haemophilia.
- With known hypersensitivity to the individual components of the product, or with infections or skin lesions in the area of the injection.
- Children, pregnant or lactating women.

Description
Hyaluronic acid (HA) is a critical substance in synovial fluid present in healthy joints, which acts as a shock absorber. A loss of hyaluronic acid associated with conditions such osteoarthritis or as a result of injury, causes symptoms such as joint pain and stiffness. Solatum™ HA Intra–articular Joint Injection Gel when injected into joint cavities can help with lubrication and buffering of damaged cartilage, suppression of inflammation, stimulation of production of high molecular HA sodium which can help with joint pain, increasing mobility, decreasing synovitis and delaying disease progression. The active substance is a highly purified sodium salt of hyaluronic acid.

Contents
Each Solatum™ HA Intra–articular Joint Injection prefilled syringe contains sodium hyaluronate in a phosphate buffered saline for a single intra-articular injection. The following volumes and concentration of HA are available: 2.0ml and 2.5ml, each of 10mg/ml and 12mg/ml.

Note: Solatum™ HA Intra–articular Joint Injection is supplied without a needle to allow the physician or healthcare professional to choose the most appropriate gauge for the injection.

Warnings
- Do not use if sterile packaging has been damaged, or if there is damage to the pre-filled syringe.
- Avoid contact with drugs containing benzalkonium chloride due to interaction.
- Do not use for intravenous injection.
- Avoid contact with instruments sterilized with quarterly ammonium salts solution or disinfectant containing quaternary ammonium salts.
- Do not use after the expiry date printed on the package.

Precautions
- The pre-filled syringe is intended for single use only. The contents of the syringe must be used immediately after the packaging is opened. Discard any unused gel. Reuse may cause infection.
- Strict aseptic administration technique must be followed to minimise danger of cross infection.
- Only for injection into the joint cavities, do not inject into synovium or ligament, to minimise pain on injection.
- If joint effusion is present, aspiration is needed before injection.
- Product should be stored in its original packaging at a temperature between 2°C – 25°C. Do not freeze.
**Directions for Use**
Clean the skin around the injection site with antiseptic and allow to dry before giving injection. If joint effusion is present it should be aspirated before injection of HA. Discard the syringe and needle after single use.

A suggested dosage regimen is injection into the affected joint space once a week for up to four injections depending on the severity of degenerative change to the knee joint. Alternatively, ad hoc injections may be given. The therapeutic effect of Solatum™ HA Intra–articular Joint Injection Gel may last for up to three months.

Transient pain and a feeling of heat may occur with intra-articular injections. These will disappear spontaneously in 2 to 3 days. If there is no improvement, then stop using and use appropriate symptomatic treatment.

**Storage Conditions**
Store between 2°C and 25°C in a well ventilated and clean area with relative humidity below 80%. Do not freeze. Protect from light. Poor storage conditions will affect the products performance or could lead to product contamination.

**Disposal**
Dispose after use in a sharps bin or appropriate container.

**Adverse Event**
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should be reported to Solatumfarma on 01922 895 262.

**Date of Preparation**
June 2019.