compatibility of Hylasto® S with other products for intra-articular use.

Side effects

Intra-articular injections of Hylasto® S may cause temporary pain, edema and/or effusion. These reactions usually clear up in a few days. If these symptoms persist for over a week, or if any other side effects occur, the patient must inform his or her physician. The physician will be able to provide appropriate treatment for these effects. Other possible typical side effects of viscosupplement injections include, inflammation, redness, swelling, skin irritation, allergic and tissue reaction.

Storage

Store between 2°C and 25°C,
Protect from light and extreme cold.

Presentation

One syringe contains 2ml of viscoelastic gel.

STERILE	Product Sterile. Sterilized using steam.
	Refer to the instructions for use.
	Single-use product. Do not reuse.
	Caution.
+2°C +25°C	Storage temperature : 2°C - 25°C.
	Keep away from sunlight

zydus

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For Consumer complaint / Query,
Contact: Customer Care Executive
at 'Marketed By Address' or
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HYLAS PI2-0423

20.0 mg/ml Sterile Viscoelastic Sodium Hyaluronate Gel For Intra-Articular Injection

(Pre-filled syringe)

Hylasto® S

Composition

Each ml of pre-filled syringe contains:

Sodium Hyaluronate	20 mg
Sorbitol	40 mg
Buffered saline solution	q.s.

Description

Hylasto® S is a viscoelastic, sterile, apyrogenic, isotonic, buffered, 2% solution of sodium hyaluronate. Sodium hyaluronate used in Hylasto® S is obtained from bacterial fermentation and presents a high mean molecular weight (MW) of 2 MDaltons.

Performance of Hylasto® S in the treatment of symptomatic osteoarthritis (OA) is achieved through high concentration and high mean molecular weight of sodium hyaluronate combined with an agent which limits HA degradation (sorbitol). This unique combination confers to this viscoelastic solution its ability to restore joint lubrication and its shock absorbing properties similar to those of the healthy synovial fluid.

Hylasto® S functions by restoring the physiological and viscoelastic properties of the synovial fluid which has progressively been lost during OA development. Therefore, Hylasto® S reduces the local pain and discomfort caused by OA, and it improves mobility of synovial joints.

Introduction

Hylasto® S is presented in a pre-filled 2ml glass syringe. The syringe is packaged in an individual protective cover. Each box contains 1 instruction leaflet.

Indications

Hylasto® S is indicated to reduce pain and improve mobility due to degenerative changes in the knee joint and other synovial joints linked to osteoarthritis.

Dosage and method of administration

Hylasto® S is administered as a single intra-articular injection. An additional injection of Hylasto® S may be performed when OA symptoms resume or for maintaining local pain management and joint function. The time period before repeating the treatment regimen depends also on physician's experience and/or severity of the affection. Treatment efficacy has been observed for at least 6 months.

Hylasto® S should be injected within the synovial cavity by a physician skilled in performing intra-articular (IA) injections. Several actions should be taken prior to injecting Hylasto® S:

- Hylasto® S gel should be at room temperature at the moment of the IA injection
- The injection site must be carefully disinfected
- Appropriate size of the needle must be used (recommendation for injection in the knee: 18 to 21 G, 2")
- The needle must be firmly attached to the luer lock collar of the syringe
- Inject accurately into the joint cavity only

Contra-indications

Hylasto® S must not be:

- used in patients with known hypersensitivity to sodium hyaluronate and/or sorbitol
- injected into an infected joint
- injected in patients with a skin disorder or an infection at the site of the injection
- injected intravascularly
- injected in pregnant or breast feeding women
- injected in young people under the age of 18 years

Precautions for use

- Before treatment the patient must be informed about the device, its contra-indications and possible side effects.
- In the absence of available clinical data on tolerance and efficacy of Hylasto® S in patients with antecedents or active auto-immune disease, or patients with an abnormal physiological condition, the physician must decide whether to inject Hylasto® S on a case-by-case basis depending on the nature of the disease as well as the associated concomitant treatments. It is also recommended to carefully monitor these patients after injection.
- Check the integrity of the inner packaging prior to use and check the expiry date. Do not use the product if the expiry date has lapsed or if the packaging has been opened or damaged.
- Do not transfer Hylasto® S into another container and do not add other ingredients to the product.
- The IA injection should be performed carefully in order to avoid injecting outside the intra-articular cavity or into the synovial membrane. Viscoelastic gels injected in the peri-synovial area can be painful due to compression on the surrounding tissues.
- It is not recommended to inject into a joint of a limb presenting important venal or lymphatic stasis.
- It is not recommended to inject into a seriously inflamed joint.
- In case of significant joint effusion, the physician must decide whether to inject Hylasto® S on a case-by-case basis. Effusion must be aspirated before injecting Hylasto® S.
- Hylasto® S is a single-use product, thus it should not be used for several patients and/or different sessions.

The product must not be resterilised. Reuse of single-use products may cause infections as the sterility is void. Only the gel is sterile but not the outside of the syringe.

- Hylasto® S must be administered under strict aseptic procedures.
- The patient is advised to avoid intense physical activity for at least 48 hours after the injection.
- Product must be stored under recommended storage conditions.
- Discard the syringe in accordance with accepted medical practice and applicable national, local and institutional requirements.

Drug interactions

There is a known incompatibility between sodium hyaluronate and quaternary ammonium salts such as benzalkonium chloride. Therefore, Hylasto® S must never come into contact with such products (e.g.: certain disinfectants), nor with medical or surgical equipment treated with these types of products. To date, no data is available on the

FRONT

BACK

Colour : Black

Size : 100 x 137 mm (L x H) / Folding size : 50 x 68.5 mm (one vertical and one horizontal fold)

\\MFGfilecl\PTC\Pkg. Dev\Commercial\ARTWORKS_COM\Domestic New logo 2022\HYLASTO\HYLAS PI2-0423_PI_Hylasto S 20 mg_ml hyaluronate Gel PFS 100x137mm.ai