TendoMAX

INSTRUCTIONS FOR USE

TendoMAX
Sodium hyaluronate 40 mg/2 ml, sterile solution for injection in pre-filled syringe

For peritendinous or intrasheath injection.

TendoMAX is a viscoelastic, isotonic, 40 mg/2 ml solution of sodium hyaluronate in a buffered physiological solution comprised of sodium phosphate, sodium chloride, and mannitol at a pH of 7 - 8. The sodium hyaluronate is purified from the bacterial fermentation of a Streptococcus strain.

Sterile by moist heat.

Indications:
For the treatment of pain and restricted mobility in tendon disorders.

Contraindications:
TendoMAX is contraindicated:
- for patients with ascertained hypersensitivity (allergy) to one of its constituents
- for patients with a history of hypersensitivity to gram positive bacterial proteins
- for patients with an active infection or skin disease near or around the injection site
- for patients who have received another injectable medicine near or around the injection site

Potential adverse events:
Local secondary phenomena such as pain, feeling of heat, bruising, redness and swelling may occur following treatment with TendoMAX.

Dosage and administration:
TendoMAX should be administered only by medical specialists trained in peritendinous or intrasheath injection technique.
Intrasheath injection:
In tendons with a sheath, inject TendoMAX into the tendon sheath in the affected area.
Peritendinous injection:
In tendons without a sheath, inject the solution along the affected tendon, but not in the tendon.

Inject TendoMAX around the affected tendon or into the affected tendon sheath once a week for a total of 2 injections. Several tendons may be treated at the same time. Repeat treatments may be administered as required.
The content of the TendoMAX pre-filled syringe is sterile.

Take the pre-filled syringe out of the pack, unscrew the cap, attach a suitable needle (e.g., 25- to 27-gauge) and secure by turning slightly.

The final needle selection for any procedure is determined by the physician. There are several factors, which need to be considered in choosing the size (gauge) and length of the needle to be used for peritendinous or intrasheath injection, including the anatomy of the region, distance between the skin and tendon, and patient characteristics (weight, age). Ultrasound guidance is recommended during injection.

Remove any air bubble, if present, before injection.

Interactions:
No information on the incompatibility of TendoMAX with other medications administered to tendons is available to date.

Precautions:
Caution should be exercised in patients with known hypersensitivity to medicinal products.
The general precautions for peritendinous and intrasheath injections should be observed. TendoMAX should be instilled accurately into the tendon sheath or around the affected tendon. The ultrasound guidance is recommended during injection.

Avoid nerve lesions and injections into blood vessels! The procedure should be avoided in patients with known systemic bleeding disorders, or in patients with history of vasovagal reaction or syncope.
As no clinical evidence is available on the use of sodium hyaluronate in children and adolescents, pregnant and lactating women, treatment with TendoMAX is not recommended in these cases.

4785

Patients who have experienced any complications in the days after injection should contact the physician immediately.

Warnings:
Single use device! Each pre-filled syringe of TendoMAX 40 mg/2 ml, solution for injection is intended to be used once only for a single patient.
Do not use if the pre-filled syringe or the blister are damaged. Any solution not used immedi-ately after opening must be discarded. Otherwise, the sterility is no longer guaranteed.
The used needles and syringes must be discarded after injection and should not be kept for other administrations. Do not re-use! Reuse of syringes or needles already used can lead to the transmission of infectious agents (including HIV and hepatitis).

4785

Do not resterilize, as this may damage or alter the product.

Strict aseptic administration technique must be followed to minimize infections at the injection site.
Injection site must be properly disinfected (70% alcohol or with another disinfectant). Disinfectants containing quaternary ammonium salts should not be u sed for skin preparation as hyaluronic acid can precipitate under such conditions.

Do not use if the product is yellow, discoloured or contains precipitates. Keep out of the reach of children!

TendoMAX is a medical device. To be used by a physician only.

Characteristics and mode of action:
A tendon is a strong structure of fibrous connective tissue designed to transmit forces from muscle to bone and resist load during muscle contraction. Tendons may be surrounded by different structures: fibrous bands, synovial sheaths, peritendon sheaths, tendon bursae. Overuse or inappropriate biomechanical stress may cause inflammation and/or degenerative changes of the tendon, leading to pain and loss of function. Lubricating the tendon could reduce pain, improve tendon function and reduce the potential for adhesions.

Because of its lubricating and viscoelastic properties, TendoMAX promotes tendon gliding and the physiological repair process. In addition, due to its macromolecular meshwork TendoMAX reduces the free passage of inflammatory cells and molecules.

TendoMAX is a transparent solution of natural and highly purified sodium hyaluronate obtained by fermentation and is devoid of animal protein. TendoMAX also contains mannitol, a free radical scavenger, which helps to stabilise the chains of sodium hyaluronate.

Presentation:
TendoMAX - One pre-filled syringe of 40 mg/2 ml.

Storage:
Do not freeze.
The product is stored at temperatures below 25°C, in original package.
Do not use after the expiry date indicated on the box!
Last revision date: June 2016

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VEMAX PHARMA

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Number of the decision on the registration of the medical device:
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CE **0050**

Explanation of Symbols	
	Consult Instructions for use
LOT	Batch code
	Use by date
	Do not re-use
STERILE	Sterilised using steam or dry heat
	Do not resterilize
25°C	Upper limit of temperature
	Do not use if package is damaged
	Manufacturer
CE	Product conform with requirements in the European Medical Device Directive
0050	Number of Notified Body