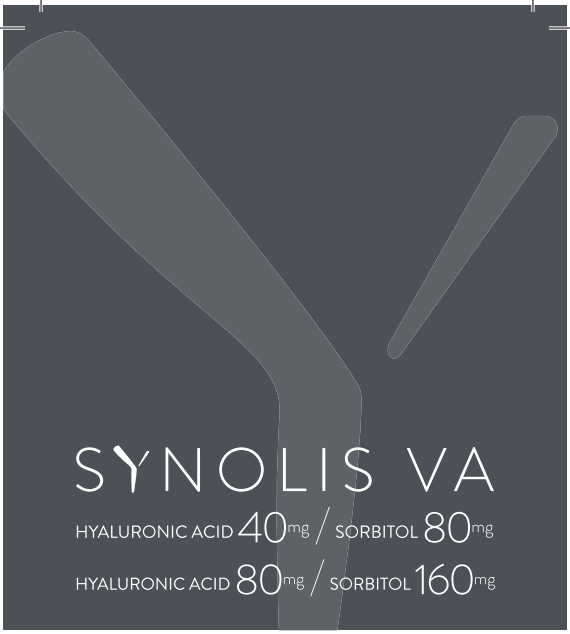

SYNOLIS VA

HYALURONIC ACID 40mg / SORBITOL 80mg

HYALURONIC ACID 80mg / SORBITOL 160mg

CE
1639

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Information as of 06/2021
Updated documentation is available from Aptissen SA.
in Switzerland.

PSL026-1

Instructions for use content of

SYNOLIS VA

EN

Description
Synolis VA is a viscoelastic, sterile, apyrogenic, isotonic, buffered, 2% solution of sodium hyaluronate. Sodium hyaluronate used in Synolis VA is obtained from bacterial fermentation and presents a high mean molecular weight (MW) of 2 MDa. Synolis VA has a neutral pH of 6.8 – 7.4 similar to the synovial fluid.
High concentration and MW of sodium hyaluronate combined with a polyol (sorbitol) that limits its degradation confer the ability of this viscoelastic solution to restore joint lubrication and shock–absorbing properties, similar to healthy synovial fluid. Synolis VA functions by restoring physiological and viscoelastic properties of the synovial fluid which has been lost progressively during the osteoarthritis (OA) development. Therefore Synolis VA reduces local pain and discomfort caused by symptomatic OA and improves mobility of the synovial joints.

Introduction
Synolis VA is available in two packagings. Each packaging includes 1 syringe, traceability labels and one instruction leaflet.

SYNOLIS VA 40/80	SYNOLIS VA 80/160
pre-filled 2ml of visco-antalgic gel in glass syringe	pre-filled 4ml of visco-antalgic gel in glass syringe

Composition
For 1 ml:

Sodium hyaluronate	20 mg
Sorbitol	40 mg
Phosphate-buffer *qs*	1 ml

The sterilisation method is moist heat.

Indications
Synolis VA is indicated for treatment of symptomatic osteoarthritis (OA), in order to reduce pain and improve mobility following degenerative changes in the synovial knee joints.

This treatment responds to patient who failed to conservative nonpharmacologic therapy and simple analgesics and/or NSAIDs or who have intolerance to simple analgesics and/or NSAIDs.

Dosage and method of administration
The treatment must be adapted depending on patient radiological and physical state (Kellgren Lawrence grade, Pain and mobility. Available clinical data have demonstrated performance of different injection regimens based on the severity of osteoarthritis:

Injection regimen / Severity	Low to moderate severity	Moderate to serious severity
1 injection of SYNOLIS VA 40/80	✓	
1 injections of SYNOLIS VA 80/160	✓	✓
3 injections of SYNOLIS VA 40/80 weekly apart.		✓

An additional injection of Synolis VA may be performed when OA symptoms resume or for maintaining local pain management and joint function. However, treatment benefits are expected to last for a minimum of 6 months for responding patients.
The time period before repeating the treatment regimen depends also on physician's experience and/or severity of the affection.

SYNOLIS VA should be injected within the synovial cavity by a physician skilled in performing intra-articular (IA) injections. Several actions should be taken prior to inject SYNOLIS VA :
•SYNOLIS VA 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 selected by the practitioner (recommendation for injection in the knee joints: 18 to 21 G),
•Appropriate size of the needle must be used (recommendation for injection in the knee joints: 18 to 21 G),
•The needle must be firmly attached to the luer lock collar of the syringe,
•Inject accurately into the joint cavity only.

Contra-indications
SYNOLIS VA must not be:
•injected in patients with known hypersensitivity or allergy to sodium hyaluronate and/or sorbitol preparation,
•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.
•Do not use Synolis VA for any indication other than symptomatic OA,
•In the absence of available clinical data on tolerance and efficacy of SYNOLIS VA in patients with antecedent or active auto-immune diseases, or patients with an abnormal physiological conditions, the physician must decide whether to inject SYNOLIS VA on a case-by-case basis depending on the nature of the disease as well as the associated concomitant treatments. It is recommended to propose a prior test to these patients and not to inject if the disease is evolving. 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 SYNOLIS VA 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 an infected or seriously inflamed joint.
•In case of significant joint effusion, the physician must decide whether to inject SYNOLIS VA on a case-by-case basis. Effusion must be aspirated before injecting SYNOLIS VA.
•SYNOLIS VA 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.
•SYNOLIS VA must be administered under strict aseptic conditions.
•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 (and the needle selected by the practitioner) 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, SYNOLIS VA 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 compatibility of SYNOLIS VA with other products for intra-articular use.

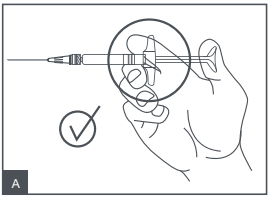
Side effects
Possible side effects exist and must be described to the patient before treatment. Slight bleeding may occur during the injection, although it stops spontaneously as soon as the injection is completed. In occasional cases one or more of the following reactions may occur either immediately or as a delayed reaction. It can be temporary local pain, oedema, and/or joint effusion. These reactions usually heal within few days. If these symptoms persist for over a week, or if any other side effects occur, the patient must inform the doctor. The doctor may prescribe appropriate treatment for these undesirable effects. Other possible typical side effects of viscosupplement injections include: inflammation, redness, swelling, skin irritation, allergic and tissue reaction.

Storage
Store between 2 and 25°C. Protect from light and extreme cold. Do not freeze the product.

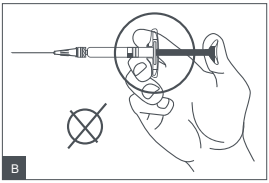
	Manufactured by.
LOT	Batch Number .
STERILE	Product Sterile. Sterilized using steam.
	Refer to the instructions for use.
2	Single-use product. Do not reuse.
	Use by date.
	Caution.
+25°C +2°C	Storage temperature : 2°C - 25°C.
	Keep away from sunlight
CE	CE marking in compliance with the directive 93/42/EEC relating to medical devices.

Syringe orientation

Hold the syringe with the opening of the finger grip (backstop) facing the palm of the hand.



Right position, Backstop opening facing the palm of the hand



Wrong position, Backstop opening at front

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Information as of 06/2021
Updated documentation is available from Aptissen SA.
in Switzerland.