

# SYNOLIS VA

HYALURONIC ACID 40<sup>mg</sup> / SORBITOL 80<sup>mg</sup>

HYALURONIC ACID 80<sup>mg</sup> / SORBITOL 160<sup>mg</sup>

希諾立關節內注射劑  
SYNOLIS VA

衛部醫器輸字第  
037325號

CE

使用前請務必詳閱原廠之使用說明  
書並遵照指示使用

1639



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Information as of 02/2020  
Updated documentation is available  
from Aptissen SA. in Switzerland.

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## 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 packaging. Those packaging include 1 syringe, traceability labels and one instruction leaflet. An implant card to be filled by the practitioner, and destined to the patient is available per product.

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

## Composition

For 1 ml:

Sodium hyaluronate	20mg
Sorbitol	40mg
Buffered saline solution q.s.p.	1ml

The sterilization 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 joints:

SYNOLIS VA 40/80	SYNOLIS VA 80/160
Knee	Knee and hips

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 regimen 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),
- 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 antecedents or active auto-immune disease, or patients with an abnormal physiological condition, 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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Storage**

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

**產品描述**

SYNOLIS VA 是一種具有黏彈性、無菌、無致熱原且等滲的 2% 透明質酸鈉緩衝溶液。所使用的透明質酸鈉是從細菌發酵中獲取，擁有平均高達 2 兆道爾頓(Mda)的平均分子量(MW)。SYNOLIS VA 是具有與滑膜液相似的中性 pH (6.8-7.4)。

將高濃度和高分子量的透明質酸鈉與限制其降解的多元醇（山梨醇）結合，可賦予這種黏彈性溶液具有與健康滑膜液相似的恢復關節潤滑及減震的能力。在骨關節炎(OA)進展期間，滑膜液的生理特性和黏彈性逐漸喪失，而本產品的作用就是恢復滑膜液的這兩種特性。因此，本產品可減少有症狀 OA 引起的局部疼痛和不適，同時改善滑液關節的活動能力。

**包裝規格**

本產品具有以下2種包裝。包裝內含一支注射器、供追溯標示的貼紙和使用說明書。

SYNOLIS VA 40/80	SYNOLIS VA 80/160
預充填2 ml黏性止痛凝膠的玻璃注射器	預充填4 ml黏性止痛凝膠的玻璃注射器

**組成**

每1毫升包含：

透明質酸鈉	20毫克
山梨醇	40毫克
緩衝磷酸鹽溶液（適量）	1毫升
滅菌方法是濕熱滅菌	

**適應症**





SYNOLIS VA 適用於治療症狀性骨關節炎 (OA)，以減少疼痛及改善下列部位滑膜關節退化性變化後的活動能力。

SYNOLIS VA 40/80	SYNOLIS VA 80/160
膝	膝、髖

此治療可用於經保守非藥物療法無效、單純鎮痛藥和/或非類固醇類消炎藥 (NSAIDs) 治療無效、或對單純鎮痛藥和/或 NSAIDs 不耐受的病患。

## 劑量及使用方法

治療必須依據病患的放射學及身體狀況 (Kellgren Lawrence 等級、疼痛和行動能力) 進行調整。現有的臨床資料已依據骨關節炎的嚴重程度顯示不同注射劑量的療效。

注射劑量/嚴重程度	嚴重程度為 輕度至中度	嚴重程度為 中度至重度
SYNOLIS VA 40/80 注射 1 次 	✓	
SYNOLIS VA 80/160 注射 1 次 	✓	✓
SYNOLIS VA 40/80 每週注射 1 次，共 3 次。   		✓

當 OA 症狀持續或用於維持局部疼痛管理和關節功能時，可額外注射一次 SYNOLIS VA。然而，對於有效的患者，預期治療效果最短可持續 6 個月。重覆此治療方案的時間，亦應取決於醫師的經驗和/或病情的嚴重程度。

本產品應由能熟練進行關節腔內 (IA) 注射的醫師注射到滑膜腔內。注射本產品之前，應完成以下幾個步驟：

- 本產品在 IA 注射時應處於室溫狀態。
- 注射部位必須嚴格消毒。
- 負責注射的醫師必須選擇適當規格的注射針。
- 必須使用適當尺寸的針頭 (推薦：18G 到 21G)。
- 針頭必須牢固的固定在注射器的螺紋接頭(Luer Lock)上。
- 僅可準確地注射到關節腔內。

## 禁忌症

不得在以下情況注射本產品

- 為已知對透明質酸鈉和/或山梨醇製劑有超敏反應或過敏的病患注射。
- 注射部位患有皮膚病或存在感染的患者。
- 血管內注射。
- 孕婦或哺乳期婦女。
- 小於 18 歲的患者。

## 使用注意事項。

- 治療前必須告知患者與本產品相關的訊息，禁忌症和可能的副作用。
- 不要將本產品用於任何症狀性 OA 症狀以外的適應症。
- 對於先前曾患有或正經歷活動性自體免疫疾病的病患，或有異常生理狀況的病患，由於當缺乏該類病患接受本產品治療的耐受性和療效的可用臨床資料，醫師必須依疾病的性質及相關的併用治療，依個案決定是否注射本產品。

建議對這些患者進行注射前檢查，如疾病正在演變，則不應注射。另外，建議在注射後對這些患者進行嚴密監測。

- 使用前檢查內包裝是否完整，並檢查保存期限。若產品過期，或者包裝被打開或破損，則不能使用。
- 不得將本產品轉移到其他容器內，也不得將其他成分添加到此產品中。
- 應小心地進行關節內注射，以避免：
  - 注射到有重要靜脈或淋巴淤滯的四肢關節內。
  - 注射到被感染或有嚴重炎症的關節內。
  - 注射到關節腔以外或滑膜內。黏彈性凝膠注射到滑膜周圍區域會因壓迫周圍組織而引起疼痛。
- 本產品必須在嚴格無菌條件下操作。
- 若出現明顯關節積液，醫師必須依個案決定是否注射本產品。注射前，必須先吸出積液。
- 本產品是一次性產品，不得用於不同患者和/或分次使用。
- 本產品不得重複滅菌。重複使用一次性產品會因無菌狀態破壞而可能導致感染。只有凝膠是無菌的，注射器的外部不是。
- 建議患者在關節內注射後至少 48 小時內避免進行劇烈活動。

### 藥品交互作用

透明質酸鈉與四級銨鹽 (Quaternary Ammonium Salt) 如苯扎氯銨 (Benzalkonium chloride) 之間，存在已知的不相容性。因此，本產品絕不能接觸此類產品 (例如：某些消毒劑)，也不適用於用這些類型的產品處理的醫療或手術設備。到目前為止，尚無數據顯示在關節內使用本產品與其他產品具相容性。

### 副作用

存在可能副作用，並應於治療前告知患者。

- 在注射過程中可能發生少量出血，但在注射結束後可迅速自發停止。
- 在極少數案例中，偶爾可能立刻或以延遲反應形式出現以下一種或多種反應：可能有暫時性局部疼痛、水腫和/或關節積液。這些反應通常在幾天內消退。如果這些症狀持續超過一周，或發生任何其他副作用，患者必須告知醫師。醫師可為這些不適反應提供適當的治療。
- 其他黏彈性補充注射可能的典型副作用包括：發炎、發紅、腫脹、皮膚刺激、過敏和組織反應。

### 貯存

請存放於2°C至25°C的環境。請避免光線照射及極度低溫。不要冷凍本產品。

### 有效期間

2年

### 製造業者名稱/地址

Manufactured by VSY Biotechnology (address: 3 Org. San. Bölgesi 3. CAD., 34959 Tepeören, Tuzla-Istanbul, Turkey) for APTISSEN SA (address: 36 Chemin du Champ des Filles, 1228 Plan-Les-Ouates, Switzerland)

醫療器材商名稱：倍斯特醫藥生物科技股份有限公司

醫療器材商地址：臺中市北屯區崇德路二段51號3樓之3、之5



Manufactured by

LOT

Batch Number

STERILE 

Product Sterile. Sterilized using steam



Refer to the instructions for use



Single-use product. Do not reuse



Use by date



Caution



Storage temperature: 2°C - 25°C



Keep away from sunlight

REF

Catalogue number

EC REP

Authorized representative in the European Community/ European Union



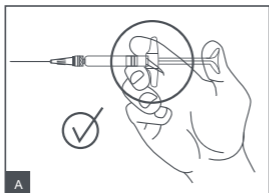
Importer



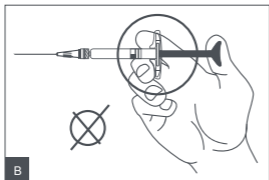
CE marking in compliance with the directive 93/42/EEC relating to medical devices

### 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

Note: 注射期間，後擋應位於正確位置

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Information as of 02/2020  
Updated documentation is available from Aptissen SA.  
in Switzerland.