

SYNOLIS VA

HYALURONIC ACID 40^{mg} / SORBITOL 80^{mg}

HYALURONIC ACID 80^{mg} / SORBITOL 160^{mg}

CE

1639



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Updated documentation is available from
Aptissen SA. in Switzerland.

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Instruction for use of content of SYNOLIS VA

GB

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 2ml of visco-antalgic gel in glass syringe	pre-filled 4ml 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.



Navodila za uporabo vsebine SYNOLIS VA

SL

Opis

SYNOLIS VA je viskoelastična, sterilna, apirogena, izotonična, pufrana 2% raztopina natrijevega hialuronata. Natrijev hialuronat, uporabljen v SYNOLIS VA, je pridobljen z bakterijsko fermentacijo in ima visoko povprečno molekulsko maso (MW) 2 MDa. SYNOLIS VA ima nevtralen pH 6,8–7,4, podoben sinovialni tekočini. Zaradi visoke koncentracije in MW natrijevega hialuronata v kombinaciji s poliolom (sorbitolom), ki omejuje njegovo razgradnjo, ima ta viskoelastična raztopina sposobnost obnoviti mazanje sklepov in lastnosti blaženja udarcev, podobno kot zdrava sinovialna tekočina. SYNOLIS VA deluje tako, da obnavlja fiziološke in viskoelastične lastnosti sinovialne tekočine, ki je bila postopoma izgubljena med razvojem osteoartritisa (OA). Zato SYNOLIS VA zmanjša lokalno bolečino in nelagodje, ki ga povzroča simptomatski OA, in izboljša gibljivost sinovialnih sklepov.

Uvod

SYNOLIS VA je na voljo v dveh pakiranjih. Obe pakiranji vključujeta 1 brizgo, nalepke za sledljivost in en izvod navodila za uporabo. Kartica o vsadku, ki jo izpolni zdravnik in je namenjena pacientu, je na voljo za vsak izdelek.

SYNOLIS VA 40/80	SYNOLIS VA 80/160
steklena brizga z 2 ml visko-antalgičnega gela	steklena brizga s 4 ml visko-antalgičnega gela

Sestava

Za 1 ml:

Natrijev hialuronat	20 mg
Sorbitol	40 mg
Pufirana fiziološka raztopina q.s.p.	1 ml
Sterilizirano z vlažno toploto.	

Indikacije

SYNOLIS VA je indiciran za zdravljenje simptomatskega osteoartritisa (OA), za zmanjšanje bolečine in izboljšanje gibljivosti po degenerativnih spremembah sinovialnih sklepov:




SYNOLIS VA 40/80	SYNOLIS VA 80/160
Koleno	Koleno in kolki

To zdravljenje je primerno za bolnike, ki se ne odzivajo na konzervativno nefarmakološko terapijo in preproste analgetike in/ ali nesteroidna protivnetna zdravila oziroma za tiste, ki ne prenašajo preprostih analgetikov in/ali nesteroidnih protivnetnih zdravil.

Odmerjanje in način vnosa

Zdravljenje je treba prilagoditi glede na radiološko in fizično stanje bolnika (stopnja po klasifikaciji Kellgren Lawrence), bolečino in mobilnost.

Razpoložljivi klinični podatki so pokazali učinkovitost različnih režimov injiciranja glede na resnost osteoartritisa:

Režim injiciranja/resnost	Nizka do zmerna resnost	Zmerna do huda resnost
1 injekcija SYNOLIS VA 40/80 	✓	
1 injekcija SYNOLIS VA 80/160 	✓	✓
3 injekcije SYNOLIS VA 40/80 s tedenskim zamikom. 		✓

Dotatno injekcijo zdravila SYNOLIS VA lahko aplicirate, ko se simptomi OA znova pojavijo ali za vzdrževanje lokalnega obvladovanja bolečine in delovanja sklepov. Vendar se pričakuje, da bodo koristi zdravljenja pri bolnikih, ki se odzivajo, trajale najmanj 6 mesecev.

Čas pred ponovitvijo režima zdravljenja je odvisen tudi od zdravnikovih izkušenj in/ali resnosti obolenja.

Zdravilo SYNOLIS VA mora v sinovialno votlino vbrizgati zdravnik, usposobljen za izvajanje intraartikularnih (IA) injicij. Pred vbrizganjem zdravila SYNOLIS VA je treba izvesti več ukrepov:

- Gel SYNOLIS VA mora biti v trenutku IA vbrizganja pri sobni temperaturi.
- Mesto vbrizganja je treba skrbno razkužiti.
- Zdravnik mora izbrati primerno velikost igle (priporočilo za vbrizganje v kolenske sklepe: 18 do 21 G).
- Igla mora biti trdno pritrjena na priključek Luer Lock brizge.
- Vbrizgajte natančno samo v sklepno votlino.

Kontraindikacije

SYNOLIS VA se ne sme:

- vbrizgati pri bolnikih z znano preobčutljivostjo ali alergijo na pripravek natrijevega hialuronata in/ali sorbitola;
- vbrizgati pri bolnikih s kožno boleznijo ali okužbo na mestu injiciranja;
- vbrizgati intravaskularno;
- vbrizgati nosečnicam ali doječim materam;
- vbrizgati pri mladih, mlajših od 18 let.

Previdnostni ukrepi za uporabo

- Pred zdravljenjem je treba bolnika seznaniti s pripomočkom, njegovimi kontraindikacijami in možnimi stranskimi učinki.
- Zdravila SYNOLIS VA ne uporabljajte za nobeno drugo indikacijo, razen za simptomatski OA.
- Ker ni razpoložljivih kliničnih podatkov o toleranci in učinkovitosti zdravila SYNOLIS VA pri bolnikih s predhodno ali aktivno avtoimunsko boleznijo ali bolnikih z nenormalnim fiziološkim stanjem, se mora zdravnik za vsak primer posebej odločiti o vbrizganju zdravila SYNOLIS VA, odvisno od narave bolezni in povezanih sočasnih zdravljenj. Priporočljivo je, da se tem bolnikom predlaga predhodni test in da se priprava ne vbrizga, če se bolezen razvija. Priporočljivo je tudi skrbno spremljanje teh bolnikov po vbrizganju.
- Pred uporabo preverite neoporečnost notranje embalaže in preverite rok uporabnosti. Izdelka ne uporabljajte, če je potekel rok uporabnosti ali če je embalaža odprta ali poškodovana.
- SYNOLIS VA ne prenašajte v drugo posodo in izdelku ne dodajajte drugih sestavin.
- IA vbrizganje je treba izvesti previdno, da se izognete injiciranju zunaj intraartikularne votline ali v sinovialno membrano. Viskoelastični geli, vbrizgani v perisinovialno področje, so lahko boleči zaradi stiskanja okoliških tkiv.
- Pripravka ni priporočljivo vbrizgati v sklep okončine s pomembnim venalnim ali limfnim zastojem.
- Ni priporočljivo vbrizgati v okužen ali resno vnet sklep.
- V primeru znatnega izliva v sklep se mora zdravnik pri posameznem primeru odločiti, ali bo vbrizgal zdravilo SYNOLIS VA. Pred vbrizganjem zdravila SYNOLIS VA je treba izliv aspirirati.
- SYNOLIS VA je izdelek za enkratno uporabo, zato se enega izdelka ne sme uporabljati za več pacientov in/ali več ločenih zdravljenj.
- Izdelka ne smete ponovno sterilizirati. Ponovna uporaba izdelkov za enkratno uporabo lahko povzroči okužbe, ker je sterilnost neveljavna. Sterilen je le gel, zunanost brizge pa ni.
- SYNOLIS VA je treba dajati v strogih aseptičnih pogojih.
- Bolniku se svetuje, naj se vsaj 48 ur po vbrizganju izogiba intenzivni telesni dejavnosti.
- Izdelek je treba hraniti pod priporočenimi pogoji shranjevanja.
- Brizgo (in iglo, ki jo je izbral zdravnik) odstranite v skladu s sprejetimi medicinskimi praksami in veljavnimi nacionalnimi, lokalnimi in institucionalnimi zahtevami.

Interakcije z zdravili

Poznana je nezdržljivost med natrijevim hialuronatom in kvarternimi amonijevimi solmi, kot je benzalkonijev klorid. Zato SYNOLIS VA nikoli ne sme priti v stik s takšnimi izdelki (npr. nekaterimi razkužili), niti z medicinsko ali kirurško opremo, obdelano s tovrstnimi izdelki. Do danes ni na voljo nobenih podatkov o združljivosti zdravila SYNOLIS VA z drugimi izdelki za intraartikularno uporabo.

Stranski učinki

Pojavijo se lahko neželeni učinki, ki jih je treba bolniku opisati pred zdravljenjem. Med vbrizganjem se lahko pojavi rahla krvavitev, ki pa se spontano ustavi takoj, ko je injiciranje končano. V občasnih primerih se lahko ena ali več od naslednjih reakcij pojavi takoj ali kot zapoznela reakcija. To je lahko začasna lokalna bolečina, edem in/ali sklepni izliv. Te reakcije se običajno pozdravijo v nekaj dneh. Če ti simptomi trajajo več kot en teden ali če se pojavijo kateri koli drugi neželeni učinki, mora bolnik obvestiti zdravnika. Zdravnik lahko predpiše ustrezno zdravljenje teh neželenih učinkov. Drugi možni tipični stranski učinki vbrizganja viskoznega dodatka vključujejo vnetje, rdečico, oteklino, draženje kože, alergijsko reakcijo in reakcijo tkiva.

Vsak resen incident, ki se zgodi v zvezi s pripomočkom, je treba prijaviti proizvajalcu in pristojnemu organu države članice, v kateri ima uporabnik in/ali bolnik sedež.

Shranjevanje

Shranjujte pri temperaturi od 2 do 25 °C. Zaščitite pred svetlobo in hudim mrazom. Izdelka ne zamrzujte.



Manufactured by

LOT

Batch Number



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



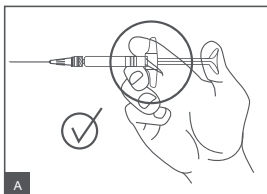
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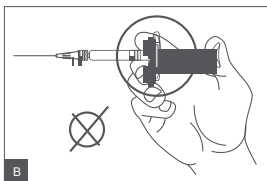
CE marking in compliance with the directive 93/42/EEC relating to medical devices

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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