DUROLANE INSTRUCTIONS FOR USE

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Read manufacturer **INSTRUCTIONS FOR USE** completely and follow the instructions prior to use.

Contents

Each ml contains:

Hyaluronic acid stabilized	20 mg
Phys sodium chloride solution, pH7	q.s.

Indications

Treatment of patients with knee osteoarthritis pain, restricted to conservative non-drug treatment and general analgesics such as Acetaminophen use invalid.

Description

DUROLANE contains 20 mg/ml of stabilized non-animal hyaluronic acid in buffered physiological sodium chloride solution pH7. DUROLANE is a sterile, transparent viscoelastic gel supplied in a 3 ml glass syringe. The product is for single use only.

Hyaluronic acid belongs to a group of very few substances which are identical in all living organisms. It is a natural poly-saccharide that is present throughout the tissues of the body, with particularly high concentrations in the synovial fluid and the skin. DUROLANE is composed of biosynthetically produced hyaluronic acid which has been purified and stabilized. DUROLANE is degraded in the body by the same metabolic pathway as endogenous hyaluronic acid.

Mode of Action

The body's hyaluronic acid constitutes a natural part of the synovial fluid and acts in the joints both as a lubricant of cartilage and ligaments and as a shock absorber. It is known that the synovial fluid in joints affected by osteoarthritis has a much lower viscosity and elasticity than in healthy joints. Injections of hyaluronic acid in the joint to restore the viscosity and elasticity can diminish the pain and improve the mobility of the joint.

Dosage

DUROLANE is a single dose preparation and should only be injected once per treatment course. The recommended dose is 3 ml (one syringe) per knee joint.

Contraindications

None known.

Warnings

- DUROLANE should not be injected if the knee joint is infected or severely inflamed.
- DUROLANE should not be injected if there is an active skin disease or infection present at or near the injection site.
- DUROLANE should not be injected intravascularly or extra-articularly or in the synovial tissues or capsule.

Precautions

- DUROLANE should be used with caution in patients with venous or lymphatic stasis present in the leg.
- DUROLANE has not been tested in pregnant or lactating women or in children.
- If treatment is bilateral, a separate syringe of DUROLANE must be used for each knee.
- As with any invasive joint procedure there is a small risk of infection when injecting DUROLANE.
- DUROLANE should not be injected if the patient is known to be sensitive to hyaluronic acid based products.
- Local anaesthetics should not be used if the patient is known to be allergic or sensitive to local anaesthetics.
- In clinical studies, reinjections in the knee have not been studied with a shorter interval between first and second injection than 6 months.
- Clinical use beyond two doses of DUROLANE has not been studied.
- DUROLANE should be used with caution in patients with pre-existing chondrocalcinosis as injection may lead to an acute attack of the condition.

Adverse Events

The majority of the reported adverse reactions in clinical studies were described as transient pain, swelling and/or stiffness–localized to the knee and were of mild or moderate intensity with a median duration of one week.

In a few patients symptoms of pain and/or swelling/stiffness localized to the knee lasted for more than 3 weeks but in these cases the observed symptoms were not distinguishable from fluctuations in the underlying osteoarthritis condition.

Adverse events must be reported to the local Bioventus representative.

Interactions

The safety and effectiveness of DUROLANE concomitantly with other intra-articular injectables have not been established.

Administration

General administration information

- DUROLANE should only be injected by an authorized physician (or in accordance with local legislation) in facilities well suited for intra-articular injections.
- DUROLANE should be injected using strict aseptic technique.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- The route for injection with DUROLANE should be chosen so that damage to adjacent vital structures is avoided.
- DUROLANE should be injected into the joint cavity only.
- Remove joint effusion, if present, before injecting DUROLANE. The same needle should be used for both removal of effusion and injection of DUROLANE.
- The recommended needle size is 18 to 22 G and with adequate length.

Please inform your patient that:

- As with any invasive joint procedure it is recommended to avoid strenuous activity (e.g. tennis, jogging or long walks) the first two days after the injection.
- Some transient reactions related to the injection of DUROLANE, such as pain and/or swelling/stiffness of mild to moderate intensity during the first week following the injection can be anticipated. If the symptoms last for more than a week a physician should be contacted.

Performance

- Clinical data indicate significant mean benefits, such as improvement in knee pain and physical function, versus baseline at 6 months post-treatment. Patients were retreated after 6 months. Retreatment did not give rise to an increased rate of adverse events.
- The half life of the product in human knees is approximately four (4) weeks, meaning that about one-fourth of the dose is left after 8 weeks.

How Supplied

DUROLANE is supplied in a 3 ml glass syringe with a Luer-lok fitting, packed in a blister pack. The contents of the syringe, stabilized non-animal hyaluronic acid gel, are sterile.

DUROLANE is intended for single use and should not be re-sterilized. It should be used immediately after the syringe has been removed from its packaging. If the blister package or syringe is opened or damaged, do not use.

Shelf life and Storage

DUROLANE should be stored, in its original packaging, up to 30 ºC. The expiry date is indicated on the package. Protect from freezing.

Manufacturing site

Q-Med AB, Seminariegatan, 21, SE-752 28 Uppsala, Sweden

For

Bioventus LLC, 4721 Emperor Blvd., Suite 100, Durham, NC 27703 USA

Company name: Emergo Taiwan Ltd. located at 10F., No.225, Sec. 3, Beixin Rd., Xindian Dist., New Taipei City 231, Taiwan

EC Representative

Emergo Europe B.V.
Molenstraat 15, 2513 BH 'S Gravenhage,
The Netherlands

IF THE PACKAGE IS DAMAGED, DO NOT USE

www.durolane.com

90-82897-01

bioventus

DUROLANE®
hyaluronic acid, stabilized single injection

膝舒適關節腔注射劑 “Bioventus” DUROLANE

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使用前請務必詳閱原廠之使用說明書並遵造指示使用。

內容

每毫升含有:

Hyaluronic acid, stabilized	20mg
Phys. sodium chloride solution, pH7	q.s

適應症

治療退化性膝關節炎疼痛患者，限用於保守性非藥物治療及一般鎮痛劑如Acetaminophen無效時使用。

產品描述

DUROLANE含有20 mg/ml 的穩定化非動物性玻尿酸(hyaluronic acid)，溶於pH7的緩衝生理食鹽溶液中。DUROLANE 為無菌透明的黏彈性凝膠，裝於3 ml的玻璃針筒中。本產品僅供單次使用。

玻尿酸屬於一群非常少數的、在所有生物中均完全相同的物質。它是一種天然的多醣類，存在於全身的組織中，在滑膜液(synovial fluid)和皮膚中的濃度特別高。DUROLANE由生物合成生產的玻尿酸組成，經過純化及穩定化。DUROLANE於體內的分解代謝途徑與內生性玻尿酸相同。

作用方式

人體中的玻尿酸構成滑膜液的天然成份，在關節中同時扮演軟骨和韌帶的潤滑劑以及吸收震動的角色。目前已知罹患骨關節炎的關節中的滑膜液，其黏性和彈性遠低於健康的關節。在關節中注射玻尿酸以回復黏性和彈性，可以消除疼痛及改善關節的活動性。

劑量

DUROLANE為單次使用製劑，每次療程只應注射一次。建議劑量是在一個膝關節中注射3 ml (一個針筒)。

禁忌症

無已知禁忌症。

警語

- 如果膝關節有感染或重度發炎時，不應注射DUROLANE。
- 如果有皮膚疾病或於注射部位附近有感染時，不應注射DUROLANE。
- DUROLANE不應注射於血管內或關節外，或注射於滑膜組織或關節囊上。

注意事項

- DUROLANE對於腿部有靜脈或淋巴滯流的病患應小心使用。
- DUROLANE未曾對懷孕或授乳中的婦女或兒童進行測試。
- 若需要雙側治療時，各膝關節必須使用不同的DUROLANE針筒。
- 與任何侵入性關節程序一樣，注射DUROLANE會有少許的感染風險。
- 如果已知病患對含玻尿酸的產品過敏時，不應注射DUROLANE。
- 如果已知病患對局部麻醉劑過敏或敏感時，不應使用局部麻醉。
- 在臨床試驗中，未曾測試第一次和第二次注射間隔少於 6 個月的膝關節重複注射。
- 臨床研究超未過兩劑使用量。
- 已有結晶沈積性關節病變(chondrocalcinosis)之患者應小心使用本產品,可能導致急性發作的症狀。

不良反應

臨床試驗中報告的不良反應，大多數為暫時性疼痛、腫脹及/或僵硬，局限於膝部，嚴重程度輕至中度，平均維持一週。

少數病患局限於膝的疼痛及/或腫脹/僵硬症狀持續超過3週，但這些病例觀察到的症狀並未與潛在的骨關節炎狀況變動有所區隔。

不良事件必須向當地Bioventus代表報告。

交互作用

DUROLANE合併其他關節內注射劑使用的安全性和藥效尚未確立。

用法

一般使用資訊

- DUROLANE只應由具備資格的醫師(或遵照當地法律規定)在適合關節內注射的設施中進行注射。
- DUROLANE注射應嚴守無菌技術。
- 注射部位於注射前應使用酒精或其他適合的消毒溶液擦拭。
- 選擇 DUROLANE注射通路時應避免傷害鄰近的重要構造。
- DUROLANE 只應注射於關節腔內。
- 注射DUROLANE前若有關節積液應移除之。移除積液和注射DUROLANE應使用同一針頭。
- 建議針頭尺寸為18到22 G，長度適足。

請告知病患:

- 和任何侵入性關節程序一樣，在注射後2天內建議避免需要施力的活動(如網球、慢跑或長途步行)。
- 注射後一週內可預期有一些相關於DUROLANE注射的暫時性反應，例如輕至中度的疼痛及/或腫脹/僵硬。如果症狀持續超過一週便應就醫。

效果

- 臨床資料顯示，治療後6個月相較於基線有顯著的平均助益，例如膝蓋疼痛及體能表現的改善。病患於6個月後再次治療，而再次治療並未導致不良事件比率上升。
- 本產品在人體膝關節中的半衰期約為4週，代表經過8週後殘留的劑量大約是4分之1。

包裝

DUROLANE裝於附有Luer-lok接頭的3 ml玻璃針筒中，以鋁箔包裝。針筒內容物－穩定化非動物性玻尿酸凝膠－已經滅菌。

DUROLANE僅供單次使用，不得重覆滅菌。自包裝中取出針筒後應立即使用。如果發現鋁箔包裝或針筒已開封或破損時請勿使用。

保存期限與儲存

DUROLANE應以原始包裝形式儲存於 30℃ 以下。保存期限標示於包裝上。請勿冷凍。

製造廠名稱及地址：Manufactured by Q-Med AB (地址：Seminariegatan 21, SE-752 28 Uppsala, Sweden) for Bioventus LLC (地址：4721 Emperor Blvd., Suite 100, Durham, NC 27703, USA)
藥商名稱: 埃默高有限公司
藥商地址: 台北市信義區信義路5段8號14樓

Symbols on packaging

	Attention, see instructions for use
	Single use only. Do not reuse
	Expiration Date
LOT	Lot number
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat. The exterior of the syringe is not sterile.
CE 0086	CE-marked according to MDD 93/42/EEC; 0086 is the number of the notified body.
EC REP	Authorised representative in the European community.
30°C 0°C	Temperature limitation.