DUROLANE® INSTRUCTIONS FOR USE

INFORMATION FOR PRESCRIBERS

CAUTION

Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

DESCRIPTION

DUROLANE® is a clear, transparent, viscous gel of highly purified, stabilized, non-animal-derived sodium hyaluronate that is biosynthesized using bacterial fermentation. NASHA technology is used to stabilize naturally entangled hyaluronic acid (HA) chains to produce a gel. The gel is suspended in phosphate-buffered saline at a concentration of 20 mg/mL.

INDICATIONS

DUROLANE® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy or simple analgesics, e.g. acetaminophen.

CONTRAINDICATIONS

- Do not inject DUROLANE® with knee joint infections, infections, or skin disease in the area of the injection site.
- Do not administer to patients with known hypersensitivity (allergy) to HA preparations.

WARNINGS

- Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because sodium hyaluronate can precipitate in their presence.
- Do not inject intra-vascularly, extra-articularly, or in the synovial tissues or capsule.

PRECAUTIONS

General

- The safety and effectiveness of DUROLANE® in joints other than the knee have not been studied.
- The effectiveness of repeated injection cycles of DUROLANE® has not been established.
- Remove any joint effusion before injecting DUROLANE®.
- Transient pain or swelling of the injected joint may occur after intra-articular injection with DUROLANE®.

- STERILE CONTENTS. EXTERIOR OF SYRINGE IS NOT STERILE. The contents of the syringe must be used immediately after its packaging is opened. Do not re-sterilize the product.
- Strict aseptic administration technique must be followed.
- Do not re-use. Dispose of the syringe and any unused DUROLANE® after use.
- Do not use if the syringe blister package is opened or damaged.
- The route for intra-articular injection should be chosen so that damage to adjacent vital structures is avoided.
- An increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.
- Local anesthetics should not be used if the patient is known to be allergic or sensitive to local anesthetic.
- DUROLANE® should be used with caution in patients with pre-existing chondrocalcinosis as injection may lead to an acute attack of the condition.
- As with any visco-supplementation treatment, the patient should avoid any strenuous activities or prolonged (i.e. more than an hour) weight bearing activities within 48 hours following intra-articular injection.

USE IN SPECIFIC POPULATIONS

- Pregnancy: The safety and effectiveness of the use of DUROLANE® have not been established in pregnant women.
- Nursing mothers: The excretion of DUROLANE® in human milk is not known. The safety and effectiveness of DUROLANE® have not been established in lactating women.
- Pediatrics: The safety and effectiveness of DUROLANE® have not been established in children (21 years of age or younger).

POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects (e.g., complications) associated with the use of this device and, in general, associated with intra-articular injection devices for the treatment of pain in osteoarthritis of the knee, include:

- Aggravated osteoarthritis
- Injection site reaction
- Arthralgia (knee pain)
- Localized osteoarthritis
- Arthropathy
- Joint (knee) disorder
- Arthrosis
- Joint (knee) swelling

- Baker's cyst
- Joint (knee) effusion
- Bursitis
- Joint (knee) stiffness
- Immune response
- Pain in limb
- Infection
- Paraesthesia
- Injection site erythema
- Phlebitis
- Injection site edema
- Pruritis
- Injection site pain
- Tendonitis

Incidences of rash, headache, dizziness, chills, hives, nausea, muscle cramps, peripheral edema, and malaise have also been reported in association with intra-articular injections.

A summary of the frequency and rate of adverse events identified in the clinical studies associated with DUROLANE®'s clinical development is provided in the "Clinical Studies" section.

CLINICAL STUDIES

Original Clinical Development Studies

The original clinical development of DUROLANE® was founded upon three randomized, controlled trials: 35GA0001, 35GA0301, and 35GA0608. The initial two trials were superiority studies versus saline; the third was a non-inferiority trial versus the commonly used corticosteroid, methylprednisolone acetate (MPA). All trials evaluated the outcome measure associated with a pain responder rate, defined as a minimum 40% reduction from baseline in WOMAC pain scores and an absolute reduction of at least 5 points in that score.

These saline controlled trials are summarized in Table 1:

Table 1. Original Clinical Development Studies-DUROLANE® vs. Saline

Clinical Study No.	n	# of Centers	Pain Responder Rate %			
			Visits	DUROLANE®	SALINE	p-value
35GA0001	DUROLANE®: 172 Saline: 174	7 US 6 Canada 5 Sweden	2 weeks	29.1	36.2	0.16
			6 weeks	36.6	29.9	0.18
			3 months	32.0	35.1	0.54
			6 months	29.1	32.2	0.53
35GA0301	DUROLANE®: 108 Saline: 110	6 Canada 4 United Kingdom 2 Germany	2 weeks	19.4	25.5	0.29
			4 weeks	26.9	26.4	0.94
			6 weeks	30.6	26.4	0.49

Neither of these saline-controlled studies demonstrated superiority over saline. Confounding factors were identified following subgroup analyses after completion of each trial. Study 35GA001included patients with poly-articular pain, making it difficult to discriminate if pain reported was from the signal knee joint versus other joints. Study 35GA0301 identified an additional confounding factor of joint effusion. The presence of effusion may signify the presence of an active inflammatory process which can lead to degradation of HA through pro-inflammatory cytokine activity.

These two studies informed the design of the third study, 35GA0608, outside of the United States comparing DUROLANE® versus MPA. Results from this study are summarized in Table 2.

Table 2: Original Clinical Development Studies-DUROLANE® vs. MPA

Clinical Study No.	# of Centers	Pain Responder Rate %			
		Visits	DUROLANE® n=221	MPA n=221	Difference 95% Confidence Interval
35GA0608	15 Canada 5 Sweden 4 UK	6 weeks	47.7	50.2	(-11.9%; +6.9%)
		12 weeks	44.6	46.2	(-11.2%; +7.9%)
		18 weeks	43.0	45.2	(-11.9%; +7.4%)
		26 weeks	43.9	36.9	(-2.5%; +16.6%)

Adverse events from these three trials are collectively presented in Table 3.

Table 3: Summary of Adverse Events Reported in Original Clinical Development Studies

Preferred Class*	**DUROLANE® All three studies (n=502)**	**MPA 35GA0608 (n=221)**	**Saline 35GA0001 and 35GA0301 (n=284)**
Related to product or injection procedure or both			
Nausea	-	2 (0.9%)	-
Pyrexia	2 (0.4%)	-	-
Injection site haematoma	-	-	2 (0.7%)
Injection site haemorrhage	-	-	1 (0.4%)
Injection site pain	15 (3.0%)	1 (0.5%)	2 (0.7%)
Injection site swelling	2 (0.4%)	-	-
Blood glucose increased	1 (0.2%)	-	-
Arthralgia	54 (10.8%)	7 (3.2%)	8 (2.8%)
Arthropathy	9 (1.8%)	-	5 (1.8%)
Joint crepitation	1 (0.2%)	-	-
Joint effusion	1 (0.2%)	1 (0.5%)	-
Joint lock	1 (0.2%)	-	-
Joint stiffness	4 (0.8%)	-	-
Joint swelling	5 (1.0%)	1 (0.5%)	-
Joint warmth	1 (0.2%)	-	-
Muscle spasms	1 (0.2%)	-	-
Pain in extremity	1 (0.2%)	1 (0.5%)	-
Sensation of heaviness	-	1 (0.5%)	-
Synovitis	1 (0.2%)	-	1 (0.4%)
Anxiety	1 (0.2%)	-	-
Depression	1 (0.2%)	-	-
Dermatitis	-	-	1 (0.4%)
Headache	2 (0.4%)	-	-
Haemarthrosis	1 (0.2%)	-	-
Myalgia	1 (0.2%)	-	-
Oedema peripheral	-	-	1 (0.4%)
Osteoarthritis	1 (0.2%)	-	-
Nervousness	1 (0.2%)	-	-

* AEs in the 35GA001 and 35GA0301 studies were classified using World Health Organisation, Adverse Reaction Terminology (WHO ART). In 35GA0608, AEs were classified using Medical Dictionary for Regulatory Activities (MedDRA).

Repeated Injection Safety of DUROLANE®

The safety of the repeated use of DUROLANE® is supported by one open label study conducted at two centers in Sweden, 35GO9901E, and an extension phase to the non-inferiority trial versus MPA, 35GA0608. In 35GA09901E, patients were offered a second injection of DUROLANE® 3 months following the initial injection and 26-weeks post-

injection in 35GA0608. The adverse event rates of the three groups were comparable, and the adverse events from these studies are summarized in Table 4.

Table 4: Summary of Related Adverse Events Reported for Repeat Injections of DUROLANE®

Preferred term*	**35GA0308 1st injection: DUROLANE® (n=163)**	**35GA0308 1st injection: MPA (n=179)**	**35GO9901E DUROLANE® (n=53)**
Related to product or injection procedure or both			
Arthralgia	30 (18.4%)	31 (17.3%)	9 (17.0%)
Arthropathy		-	2 (3.8%)
Joint dislocation	1 (0.6%)	-	-
Joint effusion	1 (0.6%)	-	-
Joint stiffness	1 (0.6%)	3 (1.7%)	-
Joint swelling	2 (1.2%)	1 (0.6%)	-
Joint warmth	-	1 (0.6%)	-
Musculoskeletal discomfort	3 (1.8%)	-	-
Urticaria	-	1 (0.6%)	-

* AEs in the 35GO9901E study were classified using World Health Organisation, Adverse Reaction Terminology (WHO ART) and Medical Dictionary for Regulatory Activities (MedDRA) for 35GA0308.

Pivotal Clinical Dataset: Comparative Study of Safety and Efficacy of Two Hyaluronic Acids for the Treatment of Knee Osteoarthritis – TG1018DLN

Study Design

Study TG1018DLN was a prospective, randomized, controlled, multicenter clinical study intended
to demonstrate that DUROLANE® was non-inferior to a commercially-available, 5-injection regimen HA product in the treatment of pain associated with knee OA over 26 weeks. A total of 349 patients were evaluated at 7 centers in the People's Republic of China. The primary outcome measure was based on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) 20-point Likert-scale . The non-inferiority margin was established as 8% (i.e., +1.6 units of the Likert-scale). Other outcome measures collected included WOMAC subscale domains of stiffness and physical function, along with subject global assessment.

Study Population

Study patients had a documented diagnosis of mild to moderate OA of the knee per the American College of Rheumatology criteria, were 40 and 80 years old, and had either Grade II or Grade III OA of the knee according to the Kellgren-Lawrence (KL) radiographic scale. Patients with KL Grades 0, I or IV, poly-articular pain, or clinically palpable knee effusions were excluded. Patients were required to have a WOMAC score between 7 and 17 at the screening and baseline visit.

Patients were randomized in a 1:1 ratio to receive either a single injection of DUROLANE® or a regimen of 5-injections of the commercially available HA over the course of 5 weeks.

Demographic and baseline characteristics were balanced between the two groups; see Table 5.

Table 5: Demographic data and baseline characteristics

		DUROLANE®	5-injection HA	TOTAL
Variable		(N=161)	(N=158)	(N=319)
Age (years)	Mean (SD)	60.2 (8.1)	60.4 (7.8)	60.3 (7.9)
	Median	60	59	59
	Min; Max	40; 78	42; 78	40; 78
Sex [n (%)]	Female	119 (73.9)	127 (80.4)	246 (77.1)
	Male	42 (26.1)	31 (19.6)	73 (22.9)
	Total	161 (100.0)	158 (100.0)	319 (100.0)
Nationality [n (%)]	Han	155 (96.3)	157 (99.4)	312 (97.8)
	Other	6 (3.7)	1 (0.6)	7 (2.2)
	Total	161 (100.0)	158 (100.0)	319 (100.0)
Weight (kg)	n	161	158	319
	Mean (SD)	66.5 (10.2)	66.8 (10.8)	66.6 (10.5)
	Median	65.0	67.0	65.0
	Min; Max	44.0; 100.0	44.5; 106.0	44.0; 106.0
Height (cm)	n	161	158	319
	Mean (SD)	162.5 (6.7)	162.4 (7.7)	162.4 (7.2)
	Median	162	160	162.0
	Min; Max	147; 183	145; 190	145; 190
BMI (kg/m^2)	n	161	158	319
	Mean (SD)	25.1 (3.2)	25.3 (3.2)	25.2 (3.2)
	Median	24.8	25.1	25.0
	Min; Max	18.4; 33.9	19.0; 35.0	18.4; 35.0
BMI classification	Underweight	1 (0.6)	0 (0.0)	1 (0.3)
	Normal range	81 (50.3)	76 (48.1)	157 (49.2)
	Overweight	65 (40.4)	69 (43.7)	134 (42.0)
	Obese	14 (8.7)	13 (8.2)	27 (8.5)
	Total	161 (100.0)	158 (100.0)	319 (100.0)

Study Treatment and Evaluation Schedule

Patients were followed for 26 weeks. Effectiveness was assessed at Weeks 6, 10, 14, 18, and 26. Safety was assessed at screening and at Weeks 0, 1, 2, 3, 4, 6, 10, 14, 18, and 26. To address patient blinding due to the different injection regimens for the products, the DUROLANE®

group was given
3 mL at Week 0 (baseline) and received subcutaneous skin punctures (i.e., the needle did not enter the joint space) with an empty syringe at Weeks 1, 2, 3, and 4. The 5-injection HA group was administered using 2.5mL injections of product at the same five time points.

Before the baseline visit, the current use of analgesics was required to have elapsed by at least 5 half-lives; within 48 hours before each visit, patients were not allowed to take any acetaminophen (paracetamol) or any other analgesic. Acetaminophen was permitted as rescue analgesia during the course of the study.

Safety Results
The safety set was comprised of 175 DUROLANE® and 174 5-injection HA subjects. Subjects with at least one treatment emergent AE were 47.4% and 42.5% in DUROLANE® and the 5-injection HA groups, respectively. The most common of these were musculoskeletal and connective tissue disorders in both groups (DUROLANE®: 25.1%; 5-injection HA: 22.4%).

Subjects with device-related AEs were 13.1% and 9.8% in the DUROLANE® and the 5-injection HA groups, respectively. The most common device-related AE was arthralgia for both groups (DUROLANE®: 8.6%; 5-injection HA: 7.5%).

The severities of device-related AEs in both groups were mainly mild and moderate; only one injection site pain in the DUROLANE® group and two cases of arthralgia and one case of joint swelling in the 5-injection HA group were classified as severe.

The percentage of subjects with Serious Adverse Events (SAEs) was 1.7% (3/175) and 3.4% (6/174) in the DUROLANE® and the 5-injection HA groups, respectively. No SAEs were considered related to the investigational products.

No deaths occurred in this study.

A summary of AEs in the safety set is outlined in Table 6.

Table 6: Summary of Adverse Events – Safety Set (SS)

	DUROLANE	**5-injection HA**
	(N=175)	(N=174)
	n (%)	n (%)
Subjects with at least one treatment emergent AE	83 (47.4)	74 (42.5) (42.5)
Subjects with device-related AEs	23 (13.1)	17 (9.8)
Subjects with a severe AE	6 (3.4)	8 (4.6)
Subjects with a SAEs	3 (1.7)	6 (3.4)
Subjects with a device-related SAE	-	-
Death	-	-

A summary of device-related AEs is outlined in Table 7.

Table 7: Device-Related Adverse Events

Primary System Organ Class (SOC) Preferred term	**DUROLANE®**	**5-injection HA**
	(N=175)	(N=174)
	n (%)	n (%)
General disorders and administration site conditions	4 (2.3)	2 (1.1)
Injection site pain	4 (2.3)	2 (1.1)
Musculoskeletal and connective tissue disorders	18 (10.3)	16 (9.2)
Arthralgia	15 (8.6)	13 (7.5)
Joint swelling	3 (1.7)	3 (1.7)
Arthropathy	1 (0.6)	-
Epicondylitis	-	1 (0.6)
Joint effusion	1 (0.6)	-
Limb discomfort	-	1 (0.6)
Muscular weakness	1 (0.6)	-
Musculoskeletal discomfort	1 (0.6)	-
Myalgia	-	1 (0.6)
Pain in extremity	1 (0.6)	-
Skin and subcutaneous tissue disorders	1 (0.6)	-
Erythema	1 (0.6)	-

Effectiveness Results

The results demonstrated that DUROLANE® was non-inferior to the 5-injection HA. The LSM (Least Squares Mean) WOMAC pain subscale score Change from Baseline (CFB) over 18 weeks was -5.97 for DUROLANE® and -5.87 for the 5-injection HA, with a difference (DUROLANE® - 5-injection HA) of -0.09 (95% CI: -0.58, 0.39). As the upper bound of the confidence interval did not exceed the pre-specified non-inferiority margin of +1.6, non-inferiority was established. See Table 8 for a tabular summary of the results of the primary endpoint by visit.

Table 8: Mixed Model Repeated Measures Analysis of WOMAC Pain Subscale Score CFB by Visit –Per Protocol Set

		Actual Result		Change from Baseline		Baseline Change Difference (95%CI)
Visit (week)		DUROLANE®	5-injection HA	DUROLANE®	5-injection HA	DUROLANE® - 5-injection HA
		(N=161)	(N=158)	(N=161)	(N=158)	
Baseline (Week 0)	Mean(SD)	9.4 (1.98)	9.5 (1.80)	N/A	N/A	N/A
Visit 7 (Week 6)	Mean(SD)	4.6 (3.32)	4.6 (2.93)	-4.9 (3.16)	-5.0 (2.68)	
	LSM (95% CI)			-5.02 (-5.46; -4.58)	-5.06 (-5.50; -4.61)	0.04 (-0.58; 0.65)
	p-value			<0.0001	<0.0001	0.91
Visit 8 (Week 10)	Mean(SD)	3.7 (3.19)	3.7 (2.81)	-5.7 (3.03)	-5.8 (2.65)	
	LSM (95% CI)			-5.45 (-5.85; -5.05)	-5.49 (-5.89; -5.09)	0.04 (-0.51; 0.59)
	p-value			<0.0001	<0.0001	0.89
Visit 9 (Week 14)	Mean(SD)	3.2 (2.90)	3.4 (2.69)	-6.2 (2.87)	-6.1 (2.59)	
	LSM (95% CI)			-5.76 (-6.14; -5.39)	-5.73 (-6.11; -5.36)	-0.03 (-0.54; 0.48)
	p-value			<0.0001	<0.0001	0.91
Visit 10 (Week 18)	Mean(SD)	3.0 (2.88)	3.3 (2.75)	-6.5 (2.79)	-6.2 (2.75)	
	LSM (95% CI)			-5.97 (-6.32; -5.61)	-5.87 (-6.23; -5.52)	-0.09 (-0.58; 0.39)
	p-value			<0.0001	<0.0001	0.70
Visit 11 (Week 26)	Mean(SD)	2.8 (2.73)	2.9 (2.68)	-6.6 (2.67)	-6.6 (2.58)	
	LSM (95% CI)			-6.15 (-6.49; -5.81)	-6.05 (-6.39; -5.71)	-0.10 (-0.56; 0.37)
	p-value			<0.0001	<0.0001	0.68

CI = confidence interval; SD = Standard deviation; LSM = Least Squares Mean

As the upper bound of the confidence interval did not exceed the pre-specified non-inferiority margin of +1.6, non-inferiority was established. See Figure 1.

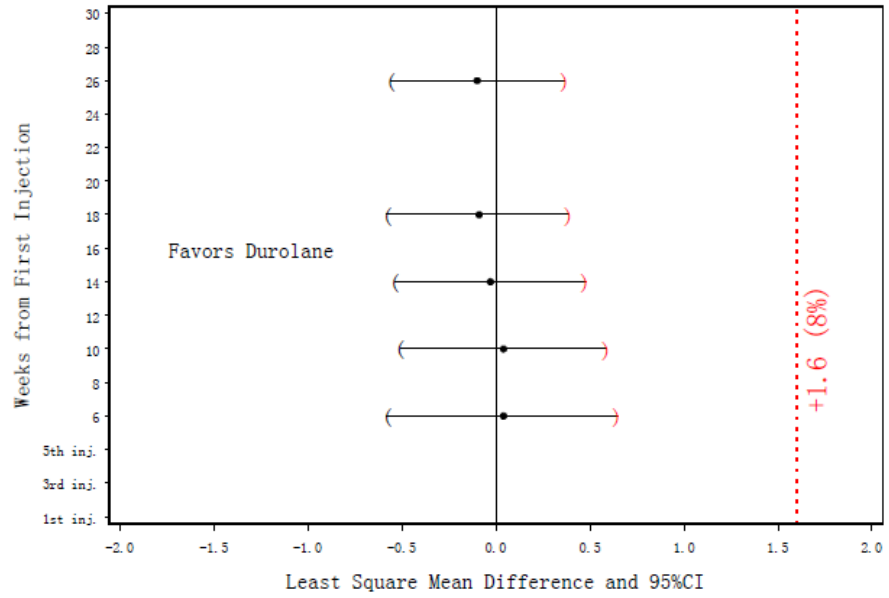

Figure 1: MMRM 95% CI Plot

MMRM 95% CI Plot of DUROLANE-5-INJECTION HA Likert-type WOMAC Pain Subscale Score-PPS

The same 8% non-inferiority margin utilized for the primary effectiveness variable was used for all secondary variables. Results through 26 weeks for the WOMAC pain subscale score CFB were included in Table 9 above.

The remaining secondary variables were tested for non-inferiority in a stepwise order as outlined in Table 10 below. All secondary effectiveness outcomes met the 8% non-inferiority criteria over the course of the study.

Table 10: Results of Stepwise Non-inferiority Analyses of Other Secondary Effectiveness Variables

Secondary Variable (order of importance)	Baseline Change Mean (SD)		(DUROLANE-5-injection HA) LSM (95%CI)	Non-Inferiority 8% Margins	Conclusion
	DUROLANE	5-injection HA			
WOMAC Physical Function CFB (over 18 weeks)	-12.75 (-13.60; -11.91)	-12.10 (-12.95; -11.26)	-0.65 (-1.81,**0.51**)	+5.44	Non-inferior
WOMAC Physical Function CFB (over 26 weeks)	-12.58 (-13.39; -11.77)	-13.16 (-13.97; -12.35)	-0.58 (-1.69,**0.53**)	+5.44	Non-inferior
Subject Global Assessment CFB (over 18 weeks)	2.70 (2.48; 2.92)	2.55 (2.33; 2.77)	0.15 (-**0.15**,0.45)	-0.8	Non-inferior
Subject Global Assessment CFB (over 26 weeks)	2.81 (2.59; 3.02)	2.67 (2.45; 2.88)	0.14 (-**0.16**,0.43)	-0.8	Non-inferior
WOMAC Knee Stiffness CFB (over 18 weeks)	-1.87 (-2.00; -1.73)	-1.73 (-1.87; -1.59)	-0.14 (-0.33,**0.05**)	+0.64	Non-inferior
WOMAC Knee Stiffness CFB (over 26 weeks)	-1.95 (-2.08; -1.82)	-1.80 (-1.93; -1.67)	-0.15 (-0.33,**0.03**)	+0.64	Non-inferior

CI = confidence interval; SD = Standard deviation; LSM = Least Squares Mean

BENEFIT-RISK ANALYSIS

A single injection of DUROLANE® provides a benefit for pain reduction in patients with osteoarthritis in the knee for up to 26 weeks. An additional benefit of DUROLANE is the ability for patients to be treated with a single injection versus a series of injections required of other multi-injection HA formulations. The results of the pivotal clinical trial supported the conclusion that the benefits of DUROLANE® in treating pain due to osteoarthritis of the knee outweigh the risks of transitory adverse events such as pain and swelling.

DETAILED DEVICE DESCRIPTION

DUROLANE® is a high molecular weight, non-animal, stabilized gel produced manufactured using NASHA technology. The device is administered as a single injection.

Each 3 mL glass syringe of DUROLANE®contains 20mg/mL of sodium hyaluronate, dissolved in phosphate buffered saline. The sodium hyaluronate is derived from bacterial fermentation (Streptococcus equi).

Each pre-filled syringe contains the following:	
Component	Each mL contains

Stabilized Sodium Hyaluronate	20mg
Sodium Chloride	9mg
Potassium Dihydrogen Phosphate	0.03mg
Disodium Hydrogen Phosphate Dihydrate	0.14mg
Water for Injection	q.s. 1mL

HOW SUPPLIED
DUROLANE® is supplied in a 3 mL, single-use glass syringe with a Luer-lok fitting, packed in a blister pack. The gel contents of the syringe have been sterilized; the exterior surfaces of the syringes are non-sterile. A needle (18-22 G) with adequate length is to be used to inject the gel into the knee joint (intra-articular space). The needle is not provided in the product package.

SHELF LIFE
36 months. DUROLANE® must be used prior to the expiry date printed on the package.

STORAGE INSTRUCTIONS
DUROLANE® should be stored, in its original packaging between 0-30 ºC (32-86ºF). Transient spikes up to 40ºC (104ºF) are permitted as long as they do not exceed 24 hours. Protect from freezing. Refrigeration is not needed.

DIRECTIONS FOR USE

1. DUROLANE® should only be injected into the diseased knee joint by an authorized physician or medical professional, familiar with intra-articular injection techniques, and in facilities well suited for intra-articular injections.

2. Prepare the injection site by swabbing the site with alcohol or another suitable antiseptic solution.

3. Use of topical or subcutaneous anesthetic may be recommended prior to injection.

4. Using an appropriate gauge needle, remove any joint effusion, if present.
   NOTE: If using the same portal for injection of DUROLANE®, the recommended needle size is 18 to 22G with adequate length. Use of smaller needles increases pressure required to deliver the product.

5. Following removal of any joint effusion, prepare product for injection; do not use if the blister package is opened or damaged.

6. To ensure a tight seal and prevent leakage during administration, secure the needle tightly while firmly holding the luer hub.

7. Inject intra-articularly into the knee synovial capsule the full contents of the syringe (i.e., 3mL). If treatment is bilateral, use a separate syringe for each knee.

8. Discard any unused DUROLANE®.

9. For single use only. Do not re-sterilize.

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