DUROLANE® SJ (small joints) INSTRUCTIONS FOR USE

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Contents

Each mL contains:

Hyaluronic acid, stabilized	20 mg
Phys. sodium chloride solution, pH 7	q.s.

Description

DUROLANE SJ (small joints) is intended to be used for intra-articular injection for the symptomatic treatment of mild to moderate osteoarthritis of indicated synovial joints, and for pain following arthroscopic procedures in the presence of mild to moderate osteoarthritis. It should be injected by an authorized physician, or in accordance with local legislation.

DUROLANE SJ contains 20 mg/mL of stabilized non-animal hyaluronic acid in buffered physiological sodium chloride solution pH 7. DUROLANE SJ is a sterile, transparent viscoelastic gel supplied in a 1 mL glass syringe. The product is for single use only.

Hyaluronic acid is identical in all living organisms. It is a natural polysaccharide that is present throughout the tissues of the body, with particularly high concentrations in the synovial fluid and the skin. DUROLANE SJ is composed of biosynthetically produced hyaluronic acid which has been purified and stabilized. DUROLANE SJ 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. 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 SJ is a **single injection**, **single dose** preparation and should only be injected once per treatment course. The recommended dose is approximately 1 mL for small synovial joints (wrist, fingers, toes), and 1-2 mL for intermediate joints (elbow, ankle). For joints requiring a 2 mL injection, an additional syringe of DUROLANE SJ will be required. DUROLANE in a 3 mL syringe is available for larger joints (refer to package insert for indications for use).

Indications

Symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, elbow, wrist, fingers, and toes. DUROLANE SJ is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.

Contraindications

DUROLANE SJ should not be injected if the patient is known to be sensitive to hyaluronic acid based products.

Warnings

- DUROLANE SJ should not be injected if the synovial joint is infected or severely inflamed.
- DUROLANE SJ should not be injected if there is an active skin disease or infection present at or near the injection site.
- DUROLANE SJ should not be injected intravascularly or extra-articularly or in the synovial tissues or capsule.
- Do not resterilize DUROLANE SJ as this may damage the product.

Precautions

- DUROLANE SJ should be used with caution in patients with venous or lymphatic stasis present in the leg.
- DUROLANE SJ has not been tested in pregnant or lactating women or in children.
- A separate syringe of DUROLANE SJ must be used for each individual joint to be treated.
- As with any invasive joint procedure there is a small risk of infection.
- Local anaesthetics should not be used if the patient is known to be allergic or sensitive to local anaesthetics.
- Injection under fluoroscopic control and with the use of a contrast medium should not be made if the patient is known to be allergic or sensitive to the contrast medium.
- In clinical studies, reinjections have not been studied with a shorter interval between first and second injection than 6 months.
- Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.
- The effectiveness of DUROLANE SJ following arthroscopic procedures for diagnosis or examination purposes only or in absence of concomitant osteoarthritis of the joint has not been established.
- DUROLANE SJ 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 joint. These adverse reactions were of mild or moderate intensity and only occasionally required treatment with painkillers or NSAIDs.

None of the other adverse reactions that have been reported were interpreted as acute inflammatory arthritis or allergic reactions and they did not need medical attention in the form of surgical intervention, systemic or intra-articular steroids or antibiotics.

Adverse events must be reported to the local Bioventus representative.

Interactions

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

Administration

General administration information

- DUROLANE SJ should only be injected by an authorized physician (or in accordance with local legislation), familiar with intra-articular injection technique for the synovial joint intended to be treated, and in facilities well suited for intra-articular injections.
- DUROLANE SJ should be injected using strict aseptic technique.
- DUROLANE SJ should be injected into the joint cavity only.
- Intra-articular injection in certain synovial joints will require image guidance to ensure accurate placement and avoidance of damage to adjacent vital structures.
- The route for intra-articular injection with or without image guidance should be chosen so that damage to adjacent vital structures is avoided.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- Remove joint effusion, if present, before injecting DUROLANE SJ. The same needle should be used for both removal of effusion and injection of DUROLANE SJ.
- The recommended needle size is 18 to 25 G and with adequate length.
- Use of smaller diameter needles increases pressure required to deliver the product.

Additional information for treatment of synovial joints requiring image guidance

- Guidance of synovial joints is at the discretion of the treating physician.
- Injection discomfort can be minimized by use of topical freezing agents or subcutaneously delivered local anaesthetics.
- Image guided injection should only be performed by physicians experienced in this type of administration.

Additional information for treatment post arthroscopy

- Following the arthroscopic procedure, intra-articular injection should be performed outside the sterile field as the exterior of the syringe is not sterile.
- Smaller joints that typically undergo arthroscopic procedures are the elbow, ankle, and wrist joints.

Please inform your patient that:

- As with any invasive joint procedure it is recommended to avoid strenuous activity the first two days after the injection.
- Some transient reactions related to the injection of DUROLANE SJ, 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 studies conducted on the ankle, shoulder, and first carpometacarpal (CMC1) joints for the treatment of osteoarthritis indicate mean benefits over baseline values. These joints represent small, intermediate, load and non-load bearing joints. The results from these studies are considered representative of the expected clinical performance of the product in the wrist, elbow, and toes due to similarities in joint size, biomechanics, and volume of product administered.
- The half-life of the product has been evaluated in both a human knee and rabbit animal model. Despite the difference in joint size and volume of product administered, both models showed a half-life of approximately four (4) weeks. The models bracket the size range of the indicated joints for the product.

How Supplied

DUROLANE SJ is supplied in a 1 mL glass syringe with a Luer-lok fitting, packed in a blister pack. The contents of the syringe are sterile. The exterior of the syringe is not sterile.

DUROLANE SJ 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. DUROLANE SJ is not supplied with needles.

The syringe and any unused material must be discarded immediately after the treatment session and must not be reused due to risk of contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

Shelf life and Storage

DUROLANE SJ should be stored, in its original packaging, up to 30ºC. The expiry date is indicated on the package and should not be used beyond that date. Protect from freezing.

Manufacturing site

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Seminariegatan 21, SE-752 28 Uppsala, Sweden

For

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4721 Emperor Blvd Suite 100
Durham, NC 27703 USA

Distributed by

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Australia

IF THE PACKAGE IS DAMAGED, DO NOT USE

For package insert information visit:
www.durolane.com

DUROLANE® SJ
hyaluronic acid, stabilized single injection

bioventus®

DUROLANE Patient Information Leaflet

Table 1: Cross Reference of Compliance of the Patient Information Leaflet with Regulation 13A.3(3)

Item	Information to be included in patient information leaflet	DUROLANE Leaflet Section
1	(a) the name of the device; and	Product Name
	(b) the model of the device	Catalog Item Numbers
2	(a) the intended purpose of the device; and	Indications
	(b) the kind of patient on whom the device is intended to be used	Benefits from DUROLANE Treatment
3	Any special operating instructions for the use of the device	Not applicable.
4	(a) the intended performance of the device; and	Intended Performance
	(b) any undesirable side effects that could be caused by use of the device	Possible Side Effects
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)	Not applicable.
6	(a) warnings about risks that could arise from the interaction of the device with other equipment; and	Not applicable.
	(b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional	Precautions Post DUROLANE Treatment Care
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and	Not applicable.
	(b) symptoms that could indicate that the device is malfunctioning; and	Serious Incidents
	(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and	Serious Incidents
	(d) the expected device lifetime; and	Duration of DUROLANE Treatment
	(e) anything that could shorten or lengthen the device lifetime; and	Not applicable.
	(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and	Not applicable.
	(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device	Post DUROLANE Treatment Care
8	(a) the materials and substances included in the device; and	Contents
	(b) any manufacturing residuals that could pose a risk to the patient	Not applicable.
9	(a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and	Serious Incidents
	(b) the address of the Therapeutic Goods Administration's website	Serious Incidents

DUROLANE® SJ

The following is summary information about the DUROLANE medical device with which you have been implanted.

Product Name:
DUROLANE SJ

Catalog Item Numbers:
DUROLANE SJ (1 mL): 1082025

CONTENTS:
Stabilized hyaluronic acid
Physiologic sodium chloride solution, pH 7

INDICATIONS:

DUROLANE SJ (1 mL):
Symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, elbow, wrist, fingers, and toes. DUROLANE SJ is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.

Benefits From DUROLANE Treatment:
If you are a patient with mild to moderate osteoarthritis who is not getting enough pain relief from oral medications, physical therapy or steroids, DUROLANE might be right for you. DUROLANE may alleviate your pain due to osteoarthritis.

Intended Performance:
DUROLANE is a single-injection treatment designed to provide pain relief when you are suffering from pain due to osteoarthritis. DUROLANE acts like a lubricant and shock absorber in the synovial fluid. A DUROLANE injection may cushion your joint and manage your symptoms.

Possible Side Effects:
The majority of the reported side effects in clinical studies were described as transient pain, swelling and/or stiffness localized to the joint. These side effects were of mild or moderate intensity and only occasionally required treatment with painkillers or NSAIDs.

Precautions:
You should not use DUROLANE if you have infections or skin disease at the injection site. DUROLANE has not been tested in pregnant or lactating women, or children.

A full listing of precautions and contraindications can be found in product labeling, at www.durolane.com or by contacting Bioventus.

Post DUROLANE Treatment Care:
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.

Duration of DUROLANE Treatment:
Clinical data indicate that patients experience benefits, such as improvement in joint pain and physical function, up to 6 months following treatment.

Serious Incidents:
If you experience any serious incident (e.g. severe pain, swelling, skin reaction) that you believe is related to DUROLANE treatment, you should contact LMT Surgical or the Australian Sponsor and the Therapeutic Goods Administration at the information provided below.

Manufacturing site
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Australian Sponsor
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Level 20, Tower II Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

Symbols on packaging

	Do not reuse
	Do not re-sterilize
0°C 25°C	Temperature limit 0-30°C
	Do not use if package is damaged
	Caution
	Use-by date
	Manufacturer
LOT	Batch code
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat. The exterior of the syringe is not sterile.

August 2019

DUROLANE® en
INSTRUCTIONS FOR USE

Contents
Each mL contains:

Hyaluronic acid stabilized	20 mg
Phys. sodium chloride solution, pH 7	q.s.

Description
DUROLANE is intended to be used for intra-articular injection for the symptomatic treatment of mild to moderate knee or hip osteoarthritis. It should be injected by an authorized physician, or in accordance with local legislation.

Additionally, DUROLANE is intended to be used for intra-articular injection for symptomatic treatment of mild to moderate osteoarthritis of indicated synovial joints, and for pain following arthroscopic procedures in the presence of mild to moderate osteoarthritis. It should be injected by an authorized physician, or in accordance with local legislation.

DUROLANE contains 20 mg/mL of stabilized nonanimal hyaluronic acid in buffered physiological sodium chloride solution pH 7. 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 polysaccharide 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 injection**, **single dose** preparation and should only be injected once per treatment course. The recommended dose is 3 mL (one syringe) per knee, hip or shoulder joint. The recommended dose is 1-2 mL for intermediate joints (e.g., elbow, ankle) and approximately 1 mL for small synovial joints (e.g. thumb).

Indications
Symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE has been approved for the symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, shoulder, elbow, wrist, fingers, and toes. DUROLANE is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.

Contraindications
DUROLANE should not be injected if the patient is known to be sensitive to hyaluronic acid based products.

Warnings
- DUROLANE should not be injected if the synovial 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.
- Do not resterilize DUROLANE as this may damage the product.

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.
- A separate synringe of DUROLANE must be used for each individual joint to be treated.
- As with any invasive joint procedure there is a small risk of infection when injecting DUROLANE.
- Local anaesthetics should not be used if the patient is known to be allergic or sensitive to local anaesthetics.
- Injection under fluoroscopic control and with the use of a contrast medium should not be made if the patient is known to be allergic or sensitive to the contrast medium.
- In clinical studies, reinjections in the knee have not been studied with a shorter interval between first and second injection than 6 months.
- Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.
- The effectiveness of DUROLANE following arthroscopic procedures for diagnosis or examination purposes only or in absence of concomitant osteoarthritis of the joint has not been established.
- 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 for treatment of knee, hip, shoulder, ankle, and metacarpal osteoarthritis were described as transient pain, swelling and/or stiffness localized to the joint. These adverse reactions were of mild or moderate intensity and only occasionally required treatment with painkillers or NSAIDs.

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.

None of the other adverse reactions that have been reported were interpreted as acute inflammatory arthritis or allergic reactions and they did not need medical attention in the form or surgical intervention, systemic or intra-articular steroids or antibiotics

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), familiar with intra-articular injection technique for the synovial joint intended to be treated, and 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.
- Use of smaller needles increases pressure required to deliver the product.

Additional information for treatment of synovial joints requiring image guidance
- The intra-articular injection in the hip joints should be given under fluroscopic control (preferrably with a contrast medium) or ultrasonographic control in order to assure correct location of the needle in the joint cavity.
- Guidance of other synovial joints is at the discretion of the treating physician.
- Injection discomfort can be minimized by use of topical freezing agents or subcutaneously delivered local anesthetics.
- Image guided injection should only be performed by physicians experienced in this type of administration.

Additional information for treatment post arthroscopy
- Following the arthroscopic procedure, intra-articular injection should be performed outside the sterile field as the exterior of the syringe is not sterile.
- Joints that typically undergo arthroscopic procedures are the knee, hip, shoulder, elbow, ankle and wrist joints.

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, hip, shoulder, ankle, and metacarpal 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.
- Controlled trials of DUROLANE in knee osteoarthritis indicates significant benefits in responder rate over saline and non-inferior results as compared to corticosteroid in a widely adopted effectiveness population of patients.
- Clinical studies conducted on the ankle, shoulder, and first carpometacarpal (CMC1) joints for the treatment of osteoarthritis indicate mean benefits over baseline values. These joints represent small, intermediate, load and non-load bearing joints. The results from these studies are considered representative of the expected clinical performance of the product in the wrist, elbow, and toes due to similarities in joint size, biomechanics, and volume of product administered.
- The half-life of the product has been evaluated in both a human knee and rabbit animal model. Despite the difference in joint size and volume of product administered, both models showed a half-life of approximately four (4) weeks. The models bracket the size range of the indicated joints for the product.

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.

The syringe and any unused material must be discarded immediately after the treatment session and must not be reused due to risk of contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

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

Manufacturing site
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IF THE PACKAGE IS DAMAGED, DO NOT USE

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DUROLANE®
hyaluronic acid, stabilized single injection

DUROLANE Patient Information Leaflet

Table 1: Cross Reference of Compliance of the Patient Information Leaflet with Regulation 13A.3(3)

Item	Information to be included in patient information leaflet	DUROLANE Leaflet Section
1	(a) the name of the device; and	Product Name
	(b) the model of the device	Catalog Item Numbers
2	(a) the intended purpose of the device; and	Indications
	(b) the kind of patient on whom the device is intended to be used	Benefits from DUROLANE Treatment
3	Any special operating instructions for the use of the device	Not applicable.
4	(a) the intended performance of the device; and	Intended Performance
	(b) any undesirable side effects that could be caused by use of the device	Possible Side Effects
5	Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)	Not applicable.
6	(a) warnings about risks that could arise from the interaction of the device with other equipment; and	Not applicable.
	(b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional	Precautions Post DUROLANE Treatment Care
7	(a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and	Not applicable.
	(b) symptoms that could indicate that the device is malfunctioning; and	Serious Incidents
	(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and	Serious Incidents
	(d) the expected device lifetime; and	Duration of DUROLANE Treatment
	(e) anything that could shorten or lengthen the device lifetime; and	Not applicable.
	(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and	Not applicable.
	(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device	Post DUROLANE Treatment Care
8	(a) the materials and substances included in the device; and	Contents
	(b) any manufacturing residuals that could pose a risk to the patient	Not applicable.
9	(a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and	Serious Incidents
	(b) the address of the Therapeutic Goods Administration's website	Serious Incidents

DUROLANE®

The following is summary information about the DUROLANE medical device with which you have been implanted.

Product Name:
DUROLANE SJ

Catalog Item Numbers:
DUROLANE (3 mL): 1082014

CONTENTS:
Stabilized hyaluronic acid
Physiologic sodium chloride solution, pH 7

INDICATIONS:

DUROLANE (3 mL):
Symptomatic treatment associated with mild to moderate osteoarthritis pain in the hip, knee, ankle, shoulder, elbow, wrist, fingers, and toes. DUROLANE is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.

Benefits From DUROLANE Treatment:
If you are a patient with mild to moderate osteoarthritis who is not getting enough pain relief from oral medications, physical therapy or steroids, DUROLANE might be right for you. DUROLANE may alleviate your pain due to osteoarthritis.

Intended Performance:
DUROLANE is a single-injection treatment designed to provide pain relief when you are suffering from pain due to osteoarthritis. DUROLANE acts like a lubricant and shock absorber in the synovial fluid. A DUROLANE injection may cushion your joint and manage your symptoms.

Possible Side Effects:
The majority of the reported side effects in clinical studies were described as transient pain, swelling and/or stiffness localized to the joint. These side effects were of mild or moderate intensity and only occasionally required treatment with painkillers or NSAIDs.

Precautions:
You should not use DUROLANE if you have infections or skin disease at the injection site. DUROLANE has not been tested in pregnant or lactating women, or children.

A full listing of precautions and contraindications can be found in product labeling, at www.durolane.com or by contacting Bioventus.

Post DUROLANE Treatment Care:
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.

Duration of DUROLANE Treatment:
Clinical data indicate that patients experience benefits, such as improvement in joint pain and physical function, up to 6 months following treatment.

Serious Incidents:
If you experience any serious incident (e.g. severe pain, swelling, skin reaction) that you believe is related to DUROLANE treatment, you should contact LMT Surgical or the Australian Sponsor and the Therapeutic Goods Administration at the information provided below.

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Australia

Symbols on packaging

	Do not reuse
	Do not re-sterilize
0°C 30° C	Temperature limit 0-30°C
	Do not use if package is damaged
	Caution
	Use-by date
	Manufacturer
LOT	Batch code
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat. The exterior of the syringe is not sterile.

August 2019