DUROLANE®
hyaluronic acid, stabilized single injection

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

PRODUCT NAME:

DUROLANE®

DUROLANE® SJ

CATALOG ITEM NUMBERS:

DUROLANE (3mL): 1082014
DUROLANE SJ (1mL): 1082025

CONTENTS:

Stabilized hyaluronic acid

Physiologic sodium chloride solution, pH 7

INDICATIONS:

DUROLANE (3mL):

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.

DUROLANE SJ (1mL):

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.

LMT Surgical:

Phone: 1 300 880 155 (AU)

0800 222 770 (NZ)

E-mail: info@lmtsurgical.com

Australian Sponsor:

EMERGO AUSTRALIA
Level 20, Tower II Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia
Tel: +61 (0) 2 9006 1662
Fax: +61 (0) 2 9006 1010

Australian Therapeutic Goods Administration:

https://www.tga.gov.au/consumers

Manufacturer Contact Information:

Bioventus LLC
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Durham, NC 27703 USA