

Deflux™ Patient Information Leaflet

PRODUCT NAME

Deflux

Deflux consists of dextranomer microspheres (50 mg/mL) in a carrier gel of non-animal stabilised hyaluronic acid (15 mg/mL).

INGREDIENTS

Deflux is made from two tissue-friendly polysaccharides (types of sugar molecules) — hyaluronic acid (HA) and dextranomer. The HA in Deflux is Non-Animal Stabilised Hyaluronic Acid (NASHA®) and is naturally broken down (biodegraded) over a short time and replaced by the body's own material, while the dextranomer remains in place longer.

INDICATIONS

Deflux is indicated for vesicoureteral reflux (VUR).

INSTRUCTIONS FOR USE

A surgeon injects Deflux in or around the ureter opening (where the ureter joins the bladder) to help prevent urine from backflowing to the kidneys.

Deflux is to be administered only by qualified surgeons experienced in the use of a cystoscope and trained in the technique of intraureteral injections.

INTENDED PERFORMANCE

Deflux gel is placed at the spot where the ureters connect to the bladder. This will help keep urine from flowing back into the ureters and kidneys. Eventually, new tissue grows around the injected material, providing long-term results.

SIDE EFFECTS / UNDESIRABLE EFFECTS

There is usually no pain after the procedure. There may be some stinging during the first few times of urination. There is a small risk of infection or urinary tract infection (UTI) and bleeding from the procedure.

Potential side effects – common:

- Blood in the urine
- Urinary tract infection
- Dysuria - discomfort with urination

Potential side effects – rare:

- Ureteral obstruction with or without dilatation of the upper urinary tract, may be delayed and appear later
- Micturition urgency and frequency - sudden or frequent urge to urinate (hypertonic bladder)
- Infection of the kidneys
- Abdominal or flank pain/ discomfort
- Foreign body reaction
- Deflux can be seen on radiographic imaging and may be mistaken for ureteral stones. Patients/ Caregivers should advise future physicians of prior treatment with Deflux.
- Fever
- Bladder irritation

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Do not be alarmed by this list of possible side effects. Many patients do not experience any of them and go back to normal activities the next day. **Be sure to call your doctor if the patient cannot urinate, has a high fever, or feels pain in his or her abdomen after returning home.**

PRECAUTIONS

Patients with the following medical conditions should not be treated with Deflux: primary refluxing megaureters with distal stenosis; uncontrolled voiding dysfunction; neurogenic bladder; bleeding disorders; hypersensitivity to hyaluronic acid products, streptococcal proteins or dextran; and those with an active urinary tract infection.

EXPECTED DEVICE LIFETIME

Deflux is intended to provide long lasting relief of vesicoureteral reflux (VUR). Many have success after one injection. In studies, one-time treatment with Deflux has been proven effective in up to 93% of children with VUR grades II – IV.

SERIOUS INCIDENTS

For product information, adverse event reports, and product complaints related to the use of Deflux, contact the Palette Life Sciences Medical Information Department, the Australian Sponsor, and the Australian Therapeutic Goods Administration at the below details:

PALETTE LIFE SCIENCES MEDICAL INFORMATION DEPARTMENT

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