Deflux® — Instructions for Use

Composition
Each ml contains:

Dextranomer	50 mg
Hyaluronic acid, stabilized	15 mg
Phys. sodium chloride solution	q.s.

Description
Deflux is a sterile, viscous gel of dextranomer microspheres and stabilized hyaluronic acid of non-animal origin constituting a biocompatible and biodegradable implant. Deflux is intended for submucosal injections in the urinary bladder and distal ureter. The stabilized hyaluronic acid acts mainly as a carrier, leaving the dextranomer microspheres at the implant site where they are gradually surrounded by host connective tissue. Deflux is supplied in a glass syringe with a luer-lock fitting containing 1 ml. Each syringe is terminally moist-heat sterilized in a pouch and packed in a paper carton. The product is for single use only. The syringe label is furnished with indicative volume markings at 0.1 ml intervals. Patient record labels are included in the package to facilitate traceability of the product.

Indications for Use
- Vesicoureteral reflux.

Contraindications
- Primary refluxing megaureters with distal stenosis
- Uncontrolled voiding dysfunction
- Neurogenic bladder
- Bleeding disorders or taking thrombolytic or anticoagulant medication
- History of hypersensitivity to hyaluronic acid-based products, streptococcal proteins or dextran
- Active urinary tract infection

Warnings
- Deflux is only intended for submucosal injections in the urinary bladder and distal ureter.
- Do not resterilize Deflux as this will damage the product.
- Do not inject intravascularly.
- Do not mix with other products.
- Deflux may be detected on radiographic imaging and act as a diagnostic confounder in the ureter.
- Do not use the product if the package is damaged.

Precautions
- Deflux should only be administered by qualified physicians experienced in the use of a cystoscope and trained in subureteral and/or intraureteric injection procedures (with Deflux or other materials).
- Do not use product if the expiration date or lot number is missing or illegible on the packaging.
- The procedure and instrumentation associated with the injection of Deflux carry an inherent risk of urinary tract infection or bleeding, as do similar urological procedures. The usual precautions associated with urological procedures performed under sterile conditions, specifically cystoscopy, should be followed.
- Prior to treatment, health care practitioners are recommended to discuss all potential risks with their patients (or their parents/guardians) and ensure their awareness of signs and symptoms of potential complications.
- In children, do not inject more than 3 ml of Deflux per ureter (6 ml total per treatment session).
- Inject slowly to avoid undue stress on the luer-lock connection which could cause leakage of the gel.
- Care should be taken with the handling of the glass syringe and needle to avoid laceration or other injury.
- In the event of accidental contamination of the device, it should be discarded.
- The safety and effectiveness of Deflux in pregnant or lactating women has not been established.
- Ureteral reimplantation or stenting procedures may be necessary to treat post-operative dilation of the upper urinary tract or ureteric obstruction of the upper urinary tract.
- Consideration should be given in patient selection with respect to specific functional and anatomical abnormalities that may lower treatment success rate; such as:
  - — Grossly dilated ureteral orifices
  - — Paraureteral (Hutch) diverticula
  - — Ureterocele
  - — Duplex ureters
  - — Patients with VUR grade V
- Consideration should be given in patient selection with respect to specific circumstances that may make the patients more susceptible to post-treatment adverse reactions; such as:
  - — Patients with immunosuppression disorder or on immunosuppressive medication
  - — Patients with autoimmune disorder

Interactions
Treatment with Deflux in combination with drugs and other medical devices has not been studied.

Adverse Events
Common procedure-related side-effects include hematuria, dysuria, and urinary tract infection.

Rare post-treatment adverse reactions include ureteral obstruction with or without hydronephrosis, urgency, frequency, pyelonephritis, abdominal pain, foreign body reaction, calcification, pyrexia, hypertonic bladder, and bladder irritation.

Postoperative dilatation of the upper urinary tract that resolves spontaneously within a few days has been observed in clinical investigations in less than 1% of treated patients. However rare cases of postoperative dilatation of the upper urinary tract with or without hydronephrosis leading to temporary placement of a ureteric stent have been reported and in some cases a ureteral reimplantation procedure has been required.

Incidental findings of injection site calcifications which have been mistaken for distal ureteral calculi on imaging studies have been reported. Treating physicians should make the patients aware of this possible diagnostic confounder in imaging studies. Future physicians should be informed that the patient had a treatment with Deflux.

Adverse events thought to be related to the product should be reported to:
Palette Life Sciences Medical Information Department
Phone: 1-800-794-401
Email: palettemc@dlss.com

Recommended Needles
Contact the local retailer for details regarding suitable needles for use with Deflux. Due to pressure-flow relationships, it is not recommended that long needles with a lumen diameter of less than 0.7 mm be used. If an improper needle is used, a possible malfunction of the device with leakage of the gel at the leur-lock connection could occur. In the treatment of vesicoureteral reflux, the Deflux Metal Needle (3.7 FR x 23 G x 350 mm) is recommended for safe and accurate administration of Deflux.

Treatment Procedure
Prior to treatment, the patient should undergo a physical examination and be thoroughly evaluated to ensure proper patient selection. The patient should be advised that Deflux may not give a permanent therapeutic result and that additional treatment sessions may be required to achieve and maintain the effect of the treatment.

Antibiotic prophylaxis in the short-term follow-up post-treatment period should be considered.

Deflux is to be administered only by qualified physicians or surgeons experienced in the use of a cystoscope and trained in the technique for subureteral and/or intraureteric injections (with Deflux or other materials).

Before injecting Deflux, the following is recommended:
1. Flush physiological sodium chloride solution through the needle.
2. Fasten the needle tightly to the syringe.
3. Remove the air from the needle by injecting the gel into the needle up to a point where a droplet is visible at the tip.

The luer-lock adapter is snapped onto the syringe and held in place with friction only. It can rotate freely or be pulled off should enough force be applied. Because of this, it is recommended that the thumb and forefinger are held firmly around both the glass syringe barrel and the luer-lock adapter when assembling the needle and syringe. To facilitate proper threading/fastening of needle hub and luer-lock adapter, both push and rotate them firmly together (see Fig. 1).

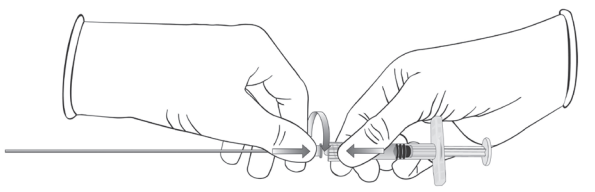

Fig. 1

To avoid any interruption in patient treatment or the need to repeat a procedure because of leakage, or accidental contamination or damage of a syringe or needle, it is recommended that extra syringes and needles be kept in inventory.

Deflux is injected through a long metal needle, see Recommended Needles, via a cystoscope with a minimum 4 French straight working channel. The material should be injected submucosally in the urinary bladder in proximity to the ureteral orifice or in the distal ureter at the 6 o'clock position. A volume of 0.5-1 ml is usually sufficient to create a prominent subureteric bulge and a crescent-like orifice. Normally 1 puncture gives a satisfactory result but in some cases 2-3 punctures may be required. Do not inject more than 3 ml at each ureteral orifice at the same treatment session. After injection, the needle should be kept in place for 15-30 seconds and withdrawn slowly to prevent extrusion of the gel.

Do not re-shield used needles. The syringe, the needle and any unused material must be discarded immediately after the treatment session and must not be reused due to risk for contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable requirements for handling of sharp devices and potential biohazards.

Shelf life and storage
The expiry date is indicated on package. Store up to 25°C. Protect from sunlight and freezing.

Legal Manufacturer:
Palette Life Sciences
27 East Cota Street, Suite 402
Santa Barbara, CA 93101 USA

Manufacturing Site:
Q-Med AB, Uppsala, Sweden

Sponsor in Australia:
Palette Life Sciences Australia Pty Ltd
Suite 2, 6-8 Waterloo Street,
NARRABEEN, NSW 2101
Australia

For product information, adverse event reports, and product complaint reports, please contact:

Palette Life Sciences Medical Information Department
Phone: 1-800-794-401
Email: palettemc@dlss.com

Symbols on the packaging


Caution


Do not reuse


Manufacturer

Deflux®

90-99860-01