



# New Device Approvals

## Deflux® Injectable Gel - P000029

*This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.*

Product Name: Deflux® Injectable Gel  
Manufacturer: Q-Med AB  
Address: Seminariegatan 21, S-752 28 Uppsala, Sweden  
Approval Date: September 24, 2001  
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000029a.pdf>

**What is it and when is it used?** Deflux® is a gel-like liquid containing complex sugars, packaged in a syringe. It is used to treat children who have vesicoureteral reflux, an abnormal condition in which urine flows backwards from the bladder to the kidneys. This condition causes repeated, severe urinary tract infections which can harm the child's kidneys

**How does it work?** A small amount of Deflux® is injected into the wall of the bladder near the opening of one or both ureters (the tubes that carry urine from the kidney to the bladder). This creates a bulge in the tissue, making it harder for the urine to flow back up the ureter. The doctor uses a special tube to see inside the bladder during the injection procedure.

**What will it accomplish?** About six out of ten children are cured of this problem by one or two injection procedures. However, there are two main side effects. About one out of six children will develop urinary tract infections again. About one out of 33 children will have his or her ureter enlarged by the procedure.

**When should it not be used?** This treatment should not be used in patients who have:

- a kidney that does not work normally,
- an abnormal pouch in the bladder wall,
- an extra ureter,
- a urinary tract infection, or
- abnormal urination.

Deflux® should never be injected into blood vessels.

**Additional information:** Summary of Safety and Effectiveness and labeling are available at:  
<http://www.fda.gov/cdrh/pdf/p000029.html>

Other:<http://www.niddk.nih.gov/health/kidney/summary/vesico/vesico.htm>

*(Updated 10/3/2001)*