

## **Bulkamid Important Safety Information (ISI) for Patients**

### INDICATION AND PATIENT TARGET GROUP

Bulkamid® Hydrogel is intended to be used as a urethral bulking agent for the treatment of female urinary incontinence where the stress component is significant. Bulkamid® Hydrogel is intended for adult female patients (above 18 years) that have failed conservative treatments.

### CONTRAINDICATIONS

Bulkamid® Hydrogel must not be used in patients suffering from acute infection in the bladder or the urinary tract (urethra), or damaged tissue in the urethra. Patients who have active herpes in the genital area must not be injected with Bulkamid® Hydrogel.

### WARNINGS OR PRECAUTIONS

There are no specific precautions or warnings for you as a patient in relation to Bulkamid® injections. Prior to the procedure, your physician will tell you about the treatment and if there are any precautions you should take, for example if you are going to have the procedure under general anaesthesia. If you should need surgery or major dental work after your treatment with Bulkamid® Hydrogel, the physician should consider antibiotic treatment to reduce the risk of infection. You should inform future healthcare professionals of your Bulkamid® treatment, as the implant can otherwise be mistaken for an illness. The efficacy of the device may diminish over time.

### SIDE EFFECTS

Contact your healthcare professional if you believe that you are experiencing side effects related to Bulkamid® Hydrogel or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed. As with any procedure there is a risk of infection, and it is therefore recommended that you receive antibiotics before the procedure. Before the procedure, your physician will tell you about the intended use, expected results, contraindications, precautions, warnings and potential side-effects. Complications may occur. These can include temporary pain during and/or shortly after the procedure (local anaesthesia will help with this), a small amount of blood in the urine, delayed urination, painful urination, and/or urinary tract infection. These complications are temporary and normally resolve within a few days. In rare cases, patients

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may experience difficulties in passing urine (retention) and may need to use a disposable catheter to empty the bladder. This normally resolves within 24 hours but in rare cases it may take days to weeks. Urge incontinence, which is a sudden and intense need to urinate, may occur. Side effects such as tissue hardening (fibrosis) loss of bulking agent (material leakage), bacterial infection (abscess) and tissue injury (necrosis) are possible, but rare. In very rare cases (<1/10,000) an infectious nodule (abscess) can form as a result of an infection (which is treated with an antibacterial agent).