

CAUTION

Federal law restricts this device to sale by or on the order of a licensed veterinarian and it must be used under the supervision of a licensed veterinarian.

PRODUCT DESCRIPTION

Mictamid® is a biocompatible, non-resorbable, injectable, transparent, hydrophilic gel intended to be injected into the submucosal tissue of the proximal urethra in female canines ≥ 5 kg.

Upon injection into the submucosal tissue, Mictamid® occupies extracellular space to increase the volume of the urethral tissue, thereby improving urethral mucosal coaptation.

Mictamid® consists of 2.5% cross-linked polyacrylamide and 97.5% non-pyrogenic water. The hydrogel is supplied in a pre-filled, sterile, 1 mL syringe with a Luer Lock fitting and a tip cap.

INTENDED USE

Mictamid® is intended to be used as a urethral bulking agent for the treatment of female canine urinary incontinence due to Urethral Sphincter Mechanism Incompetence (USMI).

Mictamid® is intended for veterinary use only.

CONTRAINDICATIONS

Mictamid® is contraindicated in:

- Animals suffering from active urinary tract infection.
- Animals who have active herpes virus.
- Animals with damaged tissue in the urethra.

WARNINGS

- Do not inject Mictamid® intravascularly. Intravascular injection may cause an embolism.
- Monitor the superficial capillaries of the mucosa when injecting the gel. If they fade, stop the injection immediately to prevent ischemia.
- Evaluate the condition of the tissue (e.g. hardness, edema, hematoma, atrophy) at the site of injection prior to treatment.
- Animals receiving anticoagulant drugs and those with underlying coagulopathy may have an increased risk of hematoma or urethral bleeding following injection.

- Keep Mictamid® in the syringe until injection.
- Do not re-sterilize Mictamid®.
- Do not use Mictamid® after the expiration date printed on the packaging.
- Do not use Mictamid® if the package is opened or damaged.

PRECAUTIONS

- A complete medical history should be obtained to determine whether the animal is an appropriate candidate for treatment with Mictamid® including screening for and exclusion of animals with an uncorrected ectopic ureter.
- The procedure may increase the risk of urinary tract infection, and scratches and injection in urethra may cause pain and hematuria.
- It is possible that tissue texture changes seen at the site of implant may later be misinterpreted for other pathology.
- Do not inject Mictamid® into sites previously injected with other bulking agents or vice versa.
- If the animal has undergone dental work or surgery, Mictamid® should not be injected until the animal is fully recovered.
- Animals with acute or chronic systemic infection must be treated with caution.
- Animals on immunosuppressive therapy must be treated with caution. Safety has not been established for animals with autoimmune diseases.
- Diabetic animals should be well regulated prior to treatment with Mictamid®.
- The effect of Mictamid® has not been evaluated in canines during pregnancy, delivery, or lactation.
- Safety and effectiveness of Mictamid® has not been established in animals with bladder diseases, like:
 - Fragile urethral mucosal lining.
 - Urethral or bladder neck strictures
 - Urethral hypermobility.
 - Detrusor overactivity.
 - Urethral prolapse.
 - Neurogenic bladder.
- Do not inject Mictamid® into other sites of the body than intended.

DOSAGE AND ADMINISTRATION

Mictamid® must be administered by a qualified veterinarian in urethral bulking injections.

The recommended dose is approximately 4-5 mL per treatment.

Mictamid® is intended for single animal use and single use. Do not re-use. Reuse increases the risk of contamination and thereby increases the risk of infection.

After use, syringes should be handled as potential biohazards. Dispose in accordance with accepted medical practice and applicable local, state and federal requirements.

DIRECTIONS FOR USE

1. Test the animal's urine in order to exclude urinary tract infection (UTI). Do not proceed if a UTI is present.
2. Administer in operating theatres or specially equipped veterinary clinics applying aseptic techniques and full anesthesia to ensure the animal's comfort during the procedure. The preferred posture of the canine for the injections is dorsal recumbency.
3. Shave the perivulvar fur, apply pre-surgical antiseptic scrub to the perivulvar skin, and use a sterile drape around the vulva to minimize infection risk.
4. Secure the 22G, 250 mm needle to the Mictamid® syringe (Luer Lock). Prime until hydrogel is visible at the tip. The needle can now be passed through the 5 Fr instrument channel on the zero-degree 2.7 mm cystoscope.
5. Insert the cystoscope into the urethra. Advance until the bladder is visualized and position the scope adjacent to the bladder neck.
6. Extend the needle into the bladder to the 2 cm mark on the needle. Withdraw the entire system (needle and cystoscope) until the needle tip is located distal to the bladder neck.
7. Retract the needle completely back into the channel while maintaining system position.
8. To obtain regular bulking around the circumference of the urethra, two injection rings (foundational and reinforcing rings) are generated in proximity. It is recommended that each injection ring is created by injecting four separate bulking injections, injecting the Mictamid® hydrogel up to the midline of the urethral lumen. Suggested locations are 7, 5, 2, and 10 o'clock.
9. Orient the bevel towards the lumen and parallel to the urethral wall. Gently press the system against urethral wall to tent the mucosa in front of the needle tip. Advance the needle into the tissue, stopping right before the 1 cm marker.

10. Inject Mictamid® hydrogel until cushion forms and the urethral tissue reaches the midline of urethral lumen. Approximately 0.5 mL is typically placed in each cushion.

11. Retract needle into channel and rotate to the next site, keeping all injections within the same plane. Repeat steps 9-10 at each site, ensuring cushions meet centrally to achieve coaptation. Approximately 2.5 mL should be used for the foundational ring.
12. Once the foundational cushions are complete, place the needle tip at the edge of a cushion. Withdraw the system while advancing the needle until the 2 cm mark is seen. The scope tip should be approximately 2 cm distal to the foundational ring. This defines the plane for the reinforcing ring.
13. Using the same suggested locations 7, 5, 2, and 10 o'clock, repeat steps 9-10 until four cushions are well developed and the second ring achieves complete coaptation. Approximately 4-5 mL of Mictamid® hydrogel should be used in total. The goal is to produce complete coaptation of the urethral mucosa at both rings.

POST-OPERATIVE PROCEDURES

Observe the animal during recovery from anesthesia, monitoring for any immediate adverse reactions.

Hematuria or passage of blood clots may be observed during the first void following the procedure. After the animal's first void, the residual urine volume should be evaluated before the animal can be discharged. It is recommended to walk the dog the first day after treatment to ensure that the animal does not suffer from urine obstruction.

COMPLICATIONS

As with any invasive procedure, there is a risk of infection at the injection site. Standard precautions associated with the implantable material should be followed.

In the event of infection, the use of broad-spectrum antibiotics and anti-inflammatories is recommended.

The injection may cause localized inflammation or irritation, leading to discomfort, pain, or swelling.

The injection may cause hematoma leading to hematuria.

There is a possibility that the injected bulking agent could extrude if it is injected too superficially in the mucosa.

Improper injection technique could lead to urethral obstruction, resulting in difficulty urinating.

INFORMATION TO THE OWNER

The owner of the animal should be informed about the indications, expected results, contraindications, precautions, warnings, and potential complications. Post-operative care instructions, including information about activity restrictions and signs of potential complications (e.g. urine obstruction), should also be provided to the owner.

The owner of the animal should be advised that in case of complications, such as difficulty urinating, the veterinarian who performed the Mictamid* injections should be contacted immediately for necessary treatment.

STORAGE

Mictamid* must be stored protected from direct sunlight. Do not freeze. Do not store unsealed syringes for later use. The expiry date is indicated on the package. Do not use the product beyond this date.

ADVERSE EVENTS

In case of an adverse event and/or product complaint, please contact Contura Vet Limited at safety@conturavet.com.

SYMBOLS USED ON PACKAGING

	Manufacturer
	Sterile Sterilized by moist heat
	Indication of Moist heat Sterile Barrier. Packaging level ensuring sterility
	Lot number
	Catalogue number
	Date of manufacture (YYYY-MM)
	Use before date printed on the label
	For single use only. Do not re-use
	Do not re-sterilize
	Keep away from sunlight
	Do not Freeze
	Do not use if package is damaged and consult instructions for use
	Consult Instructions for Use
	Federal law restricts this device to sale by or on the order of a licensed veterinarian and it must be used under the supervision of a licensed veterinarian.



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MICTAMID®

Instruction For Use

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