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.

Manufactured for:
Contura Vet Limited
Riverside One
Sir John Rogerson's Quay
Dublin 2, Ireland

Manufactured by:
Contura International A/S
Sydmarken 23
DK-2860 Soeborg
Denmark

Distributed by:
Contura Vet (USA) Inc.
3401 Mallory Lane,
Suite 100,
Franklin, TN 37067, USA

contact@conturavet.com
Phone: +1 800-689-2909

10131-001 March 2025

contura vet

MICTAMID®

Instruction For Use

contura vet

Caution
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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 acute cystitis or urethritis.
- 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.
- Do not mix Mictamid® with other substances and keep the syringe in the blister until injection.
- Do not re-sterilize Mictamid®.
- Do not use Mictamid® after the expiration date printed on the packaging.

Precautions
- A complete medical history should be obtained to determine whether the animal is an appropriate candidate for treatment with Mictamid®.
- 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 major 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.
- Do not inject Mictamid® if there is an active urinary tract infection.
- 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 use Mictamid® if the package is opened or damaged.
- 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 3-4 mL per treatment.
Mictamid® is intended for single animal use and single use. Do not re-use. Reuse increases the risk of contamination and hereby 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 surgical suite 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. Prior to passing the cystoscope with a 5 Fr instrument channel in the urethra, a capped 22-gauge (epidural) needle is passed through the instrument channel, and the cap of the needle is removed. The needle is attached to the Mictamid® syringe (Luer Lock) and the hydrogel is pushed through the syringe until it appears at the tip of the needle. Then the needle must be pulled back just inside the instrument channel until ready for injection.
5. The cystoscope is inserted into the urethra to visualize the area to ensure accurate injection of the Mictamid® hydrogel.
6. When the correct anatomic location for bulking has been identified, the needle is inserted into the proximal urethral submucosal tissue and the Mictamid® hydrogel is injected under visual observation via the cystoscope.
7. To obtain optimal bulking of the urethra, two injection rings are generated in proximity. It is recommended that each injection ring is created by three to four separate bulking injections, injecting the Mictamid® hydrogel up to the midline of the urethral lumen. The goal is to produce complete coaptation of the urethral mucosa at both rings due to the distention caused by each injection.

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 painkillers 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 be extruded if it is injected too superficially in the mucosa.

Overcorrection or improper injection technique could lead to urethral obstruction, resulting in difficulty urinating.

Information to the owner/trainer
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 report to Contura Vet Limited at **contact@conturavet.com**