

Mictamid[®]

Instruction For Use

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 non-resorbable, injectable, transparent, hydrophilic gel, for urethral bulking in mares. Mictamid[®] consists of a backbone of cross-linked polyacrylamide, with water molecules loosely bound to the polymer matrix. Nominal proportions of the Mictamid[®] gel are 2.5% cross-linked polyacrylamide and 97.5% non-pyrogenic water for injection. Mictamid[®] is biocompatible and non-biodegradable and is sterilized by moist heat.

Mictamid[®] is supplied in a pre-filled, sterile, 1 mL syringe sealed with a Luer lock fitting. It is intended to be injected with a sterile 20-23G hypodermic needle.

Mode of Action

Mictamid[®] is injected into the submucosa of the urethra.

Upon injection into the submucosa, Mictamid[®] incorporates into the surrounding tissue. It forms a cushion-like, three-dimensional and stable structure.

Mictamid[®] is intended to improve urethral coaptation.

Indication

Mictamid[®] is indicated for urethral injection into mares that pool urine.

Contraindications

Mictamid[®] is not to be injected in actively infected areas.

Mictamid[®]

Instruction For Use

Warnings

Mictamid[®] is not recommended for use in horses with acute/chronic diseases receiving treatment with systemic corticosteroids or antibiotics.

- Do not inject Mictamid[®] intravascularly. Injection into blood vessels may cause vascular occlusion leading to possible embolism.
- Do not use Mictamid[®] if the package is opened or damaged.
- Do not re-sterilize Mictamid[®].
- Do not mix Mictamid[®] with any other product.

Discontinue injection of Mictamid[®] if the superficial capillaries of the mucosa start to fade in order to avoid ischemia.

Prior assessment of the tissue is recommended before injecting Mictamid[®] into the urethra. Do not inject Mictamid[®] if the tissue is damaged.

Precautions

It is recommended that the injection site is disinfected.

Anamnesis data of ongoing infections, concomitant medication, surgery, etc. must be reviewed before injection to prevent possible infections.

Mictamid[®] should not be used in pregnant or lactating mares.

Do not use Mictamid[®] after the expiration date printed on the packaging.

The Mictamid[®] syringe is intended for single-use and single-horse only. Do not store un-sealed syringes and do not re-use. Re-use increases the risk of contamination and thereby increases the risk of infection.

Only use Mictamid[®] if the packaging is intact and undamaged.

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

Method of Administration

Mictamid[®] must be administered by a qualified veterinarian trained in these types of procedures.

Mictamid[®]

Instruction For Use

Pre-Operative Procedures

Sedate the horse to minimize stress and discomfort. For antisepsis, wash and disinfect thoroughly in a radius of 5 centimeters around the injection site.

Injection of Mictamid[®] may be performed with concurrent local anesthetic (i.e. mepivacain, lidocaine 2%).

Administration

1. Sedate and position mare in stocks.
2. Wash, disinfect, and wrap tail. Open vagina with retractor. Flush vestibular vaginal fold and urethra opening with a sterile solution.
3. Insert urinary catheter into the urethra and void bladder. Do not remove catheter.
4. Attach a sterile 20-23 gauge needle and prime the needle. Injections should be placed in the submucosa 3 cm inside the urethra, at the 9:00, 12:00, and 3:00 o'clock positions, within the same plane. If coaptation has not been achieved, place an additional injection into the 6:00 o'clock position.

Volume required depends on urethral size and conformation. Coaptation should be achieved with 3-4mls of Mictamid[®].

Peri-Operative Procedures

Remove the protective tip cap from the Mictamid[®] syringe. The syringe is firmly attached into the Luer lock socket on the 20-23 gauge hypodermic needle. Make certain that the syringe is correctly mounted prior to use.

Post-Operative Procedures

Broad-spectrum antibiotics may be administered prior to treatment to decrease the risk of infection.

The mare should be monitored until first normal urination.

Mictamid[®]

Instruction For Use

Complications

As with all transcutaneous procedures, a Mictamid[®] injection carries a risk of infection. Standard precautions such as skin preparation and sterile technique associated with the implantable material should be followed. In the event of infection, the use of broad-spectrum antibiotics is recommended as a first-line treatment. Use of any corticosteroids is contraindicated in case of infection.

Overcorrection using Mictamid[®] may lead to urinary obstruction. In the case of obstruction, the product can be removed by puncturing and squeezing. This can be done in case of overcorrection or in case of a low-grade chronic infection.

There is a risk of mild hematoma. If this reaction is not caused by infection, it is self-limiting and will resolve within 1 week.

Information to the Owner

The owner of the horse should be informed about the indications, expected results, contraindications, precautions, warnings, and potential complications. The owner of the horse should be advised that in case of complications, the veterinarian who performed the Mictamid[®] injections should be contacted immediately for necessary treatment.

Owners should be counseled that one or more repeat Mictamid[®] injection procedures may be required to achieve a satisfactory level of improvement in urinary pooling.

Complaints

Please report any malfunction or complaints to Contura Vet at Info@conturavet.com.

Storage

Do not freeze. Keep out of reach of children. Do not store un-sealed syringes for later use. Properly discard used or unsealed syringes.

Mictamid[®]

Instruction For Use

Symbols used on packaging

-  Refers to instruction for use.
-  For single use only. Do not re-use.
-  Sterile. Sterilized by moist heat.
-  Expiry date. Use before the date printed on the label.
-  Product batch number.
-  Manufacturer.
-  Keep away from direct sunlight.
-  Do not re-sterilize.
-  Do not freeze.
-  Do not use if package is damaged.