CARBOCAINE V STERILE AQUEOUS- mepivacaine hydrochloride solution Zoetis Inc.

Carbocaine®-V (mepivacaine hydrochloride injection) Sterile Aqueous Solution

Local Anesthetic with Rapid and Prolonged Effect for Use in Horses

Caution

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Mepivacaine hydrochloride, 1-methyl-2', 6'-pipecoloxylidide monohydrochloride, is a white, crystalline, odorless powder, readily soluble in water, and very stable in aqueous solution. It is available as a 2% sterile aqueous solution containing sodium chloride (for isotonicity) and 0.1% methylparaben (as preservative). The pH is adjusted with sodium hydroxide or hydrochloric acid.

CLINICAL PHARMACOLOGY

Mepivacaine hydrochloride is a potent local anesthetic whose effectiveness and safety have been well established in human medicine and dentistry. Laboratory and clinical studies in animals have confirmed its value in veterinary medicine. Its anesthetic activity is two to two and one half times that of procaine, and it is equal to or better than that of lidocaine. The compound has shown excellent tissue compatibility in laboratory animals and in horses. Moderate transient edema at the site of injection may occur in rare instances.

CARBOCAINE-V Sterile Aqueous Solution produces rapid and marked local anesthesia lasting for several hours. This enables the veterinarian to proceed with intended manipulations without delay and to complete the work under desensitization which is adequate even for prolonged operations. The innate vasoconstrictive activity of CARBOCAINE-V Sterile Aqueous Solution may be enhanced by the addition of epinephrine at 1:100,000. The addition should be carried out aseptically for current use and any unused portion should be discarded.

INDICATIONS

CARBOCAINE-V Sterile Aqueous Solution is recommended for infiltration, nerve block, intraarticular and epidural anesthesia for horses. It has also been found useful for topical anesthesia of the laryngeal mucosa prior to ventriculectomy. As with other anesthetics, the dosage varies considerably depending on the anesthetic technique, body area to be desensitized and the surgical procedure.

WARNINGS

Do not use in horses intended for human consumption. Not for human use. Keep out of reach of children.

PRECAUTIONS

When administered by a skilled person, CARBOCAINE-V Sterile Aqueous Solution may be employed

safely for local infiltration, for common nerve blocking procedures, and for intra-articular and epidural anesthesia.

The following precautions, which are observed with respect to all local anesthetics, also apply to this anesthetic. (1) Injections should always be made aseptically and with frequent aspirations. If blood is aspirated, the needle should be relocated and the injections continued cautiously. (2) When used for epidural anesthesia, care should be taken to avoid injection into the subarachnoid space. The skin should be shaved and sterilized, and the needles used must be sharp and of the proper length. (3) The depth of anesthesia should be checked by pricking the area before manipulations are begun.

DOSAGE AND ADMINISTRATION

Pharmacological studies in various species of animals, including horses, have shown that the drug produces complete and effective anesthesia at dosages that are no more than half those needed when procaine is used.

The following dosages have generally proved satisfactory in the horse and are therefore suggested as a guide:

For nerve block

(diagnosis of lameness, firing, pain relief in osteoarthritis, navicular disease)— 3 to 15 mL

For epidural anesthesia

(animal standing)— 5 to 20 mL

For intra-articular anesthesia

(removal of fracture chips, bone and bog spavin, arthritis)— 10 to 15 mL

For infiltration

(alone or in combination with nerve block or intra-articular anesthesia)— as required

For anesthesia of the laryngeal mucosa prior to ventriculectomy CARBOCAINE-V Sterile Aqueous Solution may be administered topically or by infiltration or by a combination of the two. For topical application, a total of 25 to 40 mL applied by spray (3 mL/application) is usually adequate. For infiltration, 20 to 50 mL will suffice.

HOW SUPPLIED

CARBOCAINE-V is available as 50 mL Multiple-Dose Vials.

Each mL contains 20 mg mepivacaine hydrochloride, 1 mg methylparaben as preservative, and sodium chloride for isotonicity. The pH was adjusted with sodium hydroxide or hydrochloric acid.

Store at controlled room temperature 20° to 25° C (68° to 77° F). Contents should be used within 90 days after the first dose is removed.

Approved by FDA under NADA # 100-703

Distributed by:

Zoetis Inc

Kalamazoo, MI 49007

Revised: August 2019

4020551 - PH 1085

PRINCIPAL DISPLAY PANEL - 50 mL Vial Carton



CARBOCAINE V STERILE AQUEOUS

mepivacaine hydrochloride solution

| Product Information | Product Information | | | |
|-------------------------|--------------------------------------------------|-----------------------|--------------------|--|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:54771- 3560 | |
| Route of Administration | EPIDURAL, INFILTRATION, INTRA-ARTICULAR, TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|---------------------------------|------------------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| | MEPIVACAINE HYDROCHLORIDE | 20 mg in 1 mL | |

| nactive Ingredients | | | |
|----------------------------------------|--------------|--|--|
| Ingredient Name | Strength | | |
| METHYLPARABEN (UNII: A2I8 C7HI9 T) | 1 mg in 1 mL | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | | |
| SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I) | | | |
| HYDRO CHLORIC ACID (UNII: QTT17582CB) | | | |

| F | ackaging | nckaging | | | | |
|---|------------------|-----------------------------|-----------------------------|--------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:54771-3560-1 | 50 mL in 1 VIAL, MULTI-DOSE | | | | |

| | Marketing Information | | | |
|--|-----------------------|------------------------------------------|----------------------|--------------------|
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Da |

NADA NADA100703 05/01/2014

Labeler - Zoetis Inc. (828851555)

Revised: 11/2019 Zoetis Inc.