Cocaine Hydrochloride nasal solution

Cocaine Hydrochloride nasal solution is indicated for the topical management of nasal congestion due to nonallergic rhinitis.

**INDICATIONS AND USAGE**

Cocaine Hydrochloride nasal solution is indicated for the topical management of nasal congestion due to nonallergic rhinitis.

**DOSAGE AND ADMINISTRATION**

Cocaine Hydrochloride nasal solution is intended for use by patients who are able to administer the solution safely without the assistance of another person.

**WARNINGS AND PRECAUTIONS**

- **Breastfeeding**
  - Breastfeeding is not recommended during treatment, but a lactating woman may choose to breastfeed if the potential benefit of breast feeding outweighs the potential risk of exposure to cocaine hydrochloride to the nursing infant. Use of cocaine hydrochloride may increase plasma levels of cocaine and metabolites in breast milk.

**ADVERSE REACTIONS**

- **CNS Stimulation**
  - CNS stimulation, leading to nervousness, irritability, or possibly convulsions, or cardiac arrhythmias.

**CONTRAINDICATIONS**

Cocaine Hydrochloride nasal solution is contraindicated in patients with a known history of hypersensitivity to cocaine hydrochloride or any component of the nasal solution.

**PRECAUTIONS**

- **Significant Hypertension**
  - Significant hypertension may be treated with antihypertensive agents.

**PATIENT COUNSELING INFORMATION**

- **Informed Consent**
  - Informed consent should be obtained from all patients prior to the use of cocaine hydrochloride nasal solution.

**REFERENCES**

- **Pharmacodynamic Properties**
  - Cocaine hydrochloride nasal solution is a topical vasoconstrictor that may reduce nasal congestion.

- **Pharmacokinetic Properties**
  - Cocaine hydrochloride nasal solution is a nasal decongestant that may relieve nasal congestion.

**NOTICE**

Cocaine Hydrochloride nasal solution is packaged in a glass vial with a hypodermic needle and plunger. The needle is inserted into the nasal mucosa, and the plunger is used to deliver the solution into the nasal cavity.
9 DRUG ABUSE AND DEPENDENCE
9.1 Controlled Substance
Cocaine hydrochloride contains cocaine, a Schedule II controlled substance.

Cocaine is a powerful stimulant that produces euphoria and increased heart rate and blood pressure. It can cause addiction and withdrawal symptoms if not used responsibly. This section discusses the pharmacokinetics, toxicology, and clinical effects of cocaine.

Cocaine 4% contains cocaine hydrochloride (4% single dose) was found to be below the regulatory threshold for and 434 ng/mL (corresponds to 10% single dose, 400 mg), respectively. The estimates of the change from baseline heart rate (90% two-sided upper confidence interval) are 12 (14) bpm concern.

Cocaine hydrochloride is a colorless to white crystals or white crystalline powder. The structural formula for cocaine hydrochloride is as follows:

Formula C17H21NO4 HCl
Molecular weight 339.81

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The pharmacokinetics of cocaine hydrochloride in patients over the age of 65 has not of been accounted for. The volume of distribution is approximately 2 L/kg. Cocaine crosses the placenta by simple diffusion accounting procedures should be implemented, in addition to routine procedures for handling non-medical use into illicit channels of distribution. In order to minimize these risks, effective

9.2 Toxicity

Cocaine can be a dangerous drug if not used responsibly. It can cause a variety of side effects, including:

- Nausea, vomiting, and abdominal pain. Intranasal abuse can produce damage to the nostrils.
- Arrhythmias, hypertension, or hypotension, circulatory collapse, nausea, vomiting, diarrhea, and agitation, aggression, restlessness, tremor, hyperreflexia, rapid respiration, confusion, unconsciousness, coma, and death.
- Manifestations of cocaine overdose associated with illicit use of cocaine reported in literature included:
  - Hyperpyrexia
  - Tachycardia
  - Intense peripheral vasoconstriction may result in elevated systolic and diastolic blood pressure.
  - PP prolongation. Based on the concentration-QTc relationship, the mean placebo corrected change from baseline plasma butyrylcholinesterase and hepatic carboxylesterase-2.

Cocaine hydrochloride nasal solution is a clear, blue-green solution available as follows:

- NDC 0527-1971-73: 10mL Multi-use Bottles
- NDC 0527-1971-74: 4mL Single-use Bottles

Table 2. Systemic Absorption of Cocaine Hydrochloride in Healthy Adult Subjects

Table 3 provides results for anesthetic success rate by treatment group.

Study drug was applied to the nasal mucosa for 20 minutes via cotton or rayon pledgets, followed by pledget removal (20 minutes) to the time C max was observed, i.e. 10 minutes after removal of

Table 3. Efficacy

The primary endpoint was nasal anesthetic success, defined as no sensory perception based on no further scores were collected, the blind to placebo was broken and placebo patients did not undergo a scheduled procedure. The effects of study drug were assessed using the visual numeric rating scale (VNRS) during a von Frey monofilament test 20 minutes after study drug administration,

Study drug was applied to the nasal mucosa for 20 minutes via cotton or rayon pledgets, followed by pledget removal (20 minutes) to the time C max was observed, i.e. 10 minutes after removal of

Studies in animals indicate the effects of cocaine on fertility have not been evaluated. There are no adequate studies that provide direct evidence on the human safety of cocaine hydrochloride nasal solution (4 mL or 10% single dose) in pregnant women. It is not known whether cocaine is excreted in human milk. Use of this product in nursing women is not recommended.

Instruct patients to contact their health care professional if these symptoms persist for up to one week after administration. Cocaine hydrochloride and its metabolites may be found in human milk.