PCCA LoxaSperse®

Patent Pending Technology

Powder Excipient Base for Use in Nasal Nebulization and Irrigation Compounds

PCCA # 30-4701



Attack chronic sinus problems where they live.

LoxaSperse can be a real game changer for patients suffering from chronic, recurrent or resistant sinus conditions. This innovative powder base for nasal nebulizations and irrigations was created to go right to the desired site of action.

In contrast to oral medications, which have to circulate throughout the entire body and may not provide adequate concentrations of active pharmaceutical ingredients (APIs) at the site of infection, LoxaSperse is used in intranasal formulations that directly target sinus problems.

Also, third party in vitro testing has shown that LoxaSperse:

- May have synergistic activity with common antimicrobial agents
- May improve activity of APIs against biofilms

BENEFITS

- Topical delivery to the nasal and sinus cavities when reconstituted
- Reduced particle size of APIs
- · Increased dispersibility and solubility of APIs
- Enables multi-drug therapy
- Formulated without preservatives
- Prolonged beyond-use date
- In a powder/capsule preparation making it easy to store and carry



FORMULATED WITHOUT

• Preservatives

RELATED SPECIALTIES

- Ear, Nose and Throat Specialists
- Allergists
- General Practice

COMMONLY COMPOUNDED WITH

- Antifungals
- Antihistamines
- Antibiotics
- · Anesthetics
- Corticosteroids

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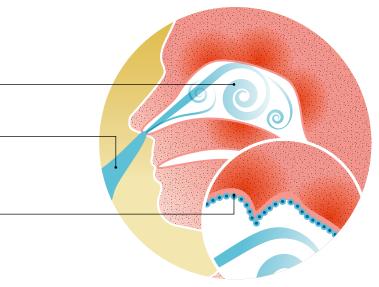


MODE OF ACTION

A proprietary blend of micronized xylitol and poloxamers reduces particle size and improves dispersibility and solubility of APIs.

LoxaSperse reconstituted with saline or sterile water applied through nasal nebulization or irrigation.

Smaller particle size and uniform dispersal of APIs may increase surface area contact with the nasal cavity and may improved API delivery.



FORMULA EXAMPLES

- PCCA Formula #10341
 Budesonide 0.5 mg Capsules Size #1 (LoxaSperse)
- PCCA Formula #11603
 Budesonide 0.5 mg Capsules Size #1 (XyliFos/LoxaSperse)
- PCCA Formula #10344
 Mometasone Furoate 0.6 mg Capsules Size #1 (LoxaSperse)
- PCCA Formula #10517
 Acetylcysteine 100 mg Capsules Size #0 (LoxaSperse)
- PCCA Formula #10552
 Amphotericin B 10 mg Capsules Size #1 (LoxaSperse)
- PCCA Formula #11623
 Amphotericin B 10 mg Capsules Size #1 (XyliFos/LoxaSperse)
- PCCA Formula #11983
 Gentamicin 80 mg/Mupirocin 30 mg/Edetate Disodium
 15 mg Capsules (XyliFos/LoxaSperse)
- PCCA Formula #14173
 Itraconazole 50 mg Capsules Size #1 (LoxaSperse)
 (FlackTek SpeedMixer®)

• PCCA Formula #11973

Doxycycline 20 mg/Phenytoin 20 mg/Lidocaine HCl 10 mg/Misoprostol 0.024 mg Wound Care Capsules Size #1 (XyliFos/LoxaSperse)

ALSO AVAILABLE

PCCA XyliFos®

An excipient base developed to be used in combination with LoxaSperse to maximize the solubilizing/dispersing properties and antimicrobial synergy.

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FREQUENTLY ASKED QUESTIONS

How are LoxaSperse preparations dispensed?

LoxaSperse preparations can be dispensed as capsules or powder sachets. At the time of use, the capsule or packet is opened and the contents are then mixed with an appropriate amount of sterile water (~5-15 mL). The preparation is then ready to be administered via a nasal nebulization/irrigation device.

How is LoxaSperse used in formulations?

LoxaSperse is used as the QS excipient filler. It is recommended to use LoxaSperse at a mininum amount of 25% of the capsule volume in formulations to obtain the maximum solubilizing/dispersing properties.

What is a nasal nebulization/irrigation device?

One example of a device is the commercially available NasoNeb. PCCA does not sell this item; refer to NasoNeb's website for more information: nasoneb.com.

What is the best way for the patient to mix the LoxaSperse capsule or sachet contents with water?

Use a prescription bottle or plastic cup (sterile, unused urine cups work well). Empty contents into the bottle or cup and add sterile water. Mix by swirling gently until a uniform suspension or solution is obtained (less than a minute). Some APIs may create foam when mixed with water. If this occurs, swirl the preparation gently until foam has subsided. Pour contents into the nebulization/irrigation device cup. Help patients with this by not locking the capsules after the capsules have been filled and the lids attached. This will make it easier for the patient to open at the time of mixing.

When do you use sterile water versus saline?

Most formulations with LoxaSperse are already hypertonic when solubilized, so sterile water is a good choice unless otherwise specified.

Is LoxaSperse safe for pregnant or nursing women?

It has not been studied.

Is LoxaSperse sterile?

No, LoxaSperse powder formulations are dispensed nonsterile and mixed with sterile water only at time of use.

Is there a substitution for LoxaSperse?

No, there is not another ingredient or combination of ingredients that can replace the action of LoxaSperse for improving solubility and dispersibility. However, using it in conjunction with PCCA XyliFos® (PCCA Document #99006) may provide dissolution/dispersing synergy, along with reducing overall cost. In some cases, saving up to 50% on the cost of preparing a prescription.

CONTROLLED STUDIES

- Journal Article: Characterization of the Properties of Powder Excipients Commonly Used in Pharmaceutical Compounding
- 2. Technical Report: Characterization of the Physical and Microbiological Properties of LoxaSperse
- 3. Technical Report: The Antimicrobial Activity of Itraconazole and LoxaSperse Against Biofilms of *C. albicans*

To see all of our LoxaSperse studies in depth, visit <u>PCCA</u> <u>Document #98669</u>.

PLEASE NOTE

Always make sure you have checked the PCCA formula database and are following the most up-to-date version of a formula, as changes are continually made to existing formulations to provide the highest quality. The formulas and/or statements listed are provided for educational purposes only. They are compounding ideas that have commonly been requested by physicians and have not been evaluated by the Food and Drug Administration. Formulas and/or material listed are not to be interpreted as a promise, guarantee, or claim of therapeutic efficacy or safety. The information contained herein is not intended to replace or substitute for conventional medical care or encourage its abandonment. Every patient is unique, and formulas should be adjusted to meet their individual needs.

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