



Mucosal Delivery System for Use in Compounding

PCCA # **30-4782**



Staying Power.

MucoLox is a revolutionary mucosal delivery system that provides long-lasting coverage and improves contact time. This innovative base can be used with active pharmaceutical ingredients (APIs) in a variety of potential formulations, including oral, rectal, vaginal and esophageal/gut preparations as well as wound care.

MucoLox's one-of-a-kind polymer network provides improved moisturization, mucoadherence and superior film forming action, but won't easily wash away, bonding to the mucosa to create a powerful but lightweight coating effect. When used with APIs, MucoLox's advanced adhesive properties improve contact time of the API to the mucosa.

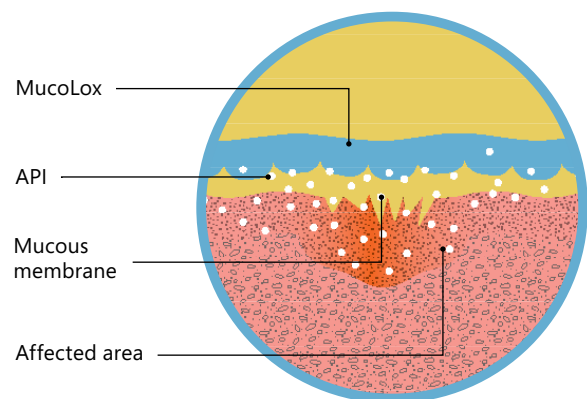
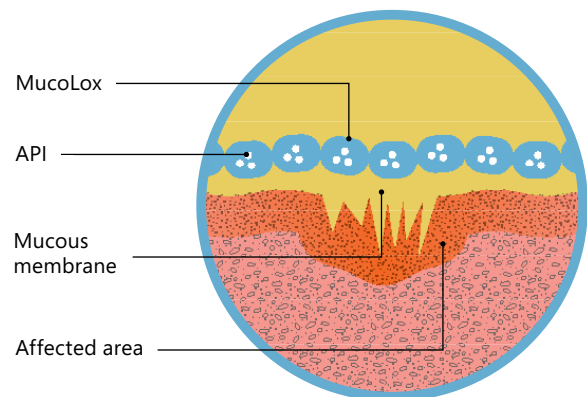
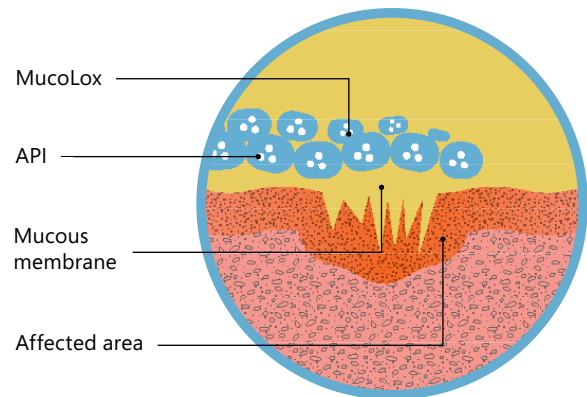
It's a great option for patients suffering from conditions like mouth ulcers (including those resulting from cancer treatment), esophagitis and more.

MucoLox has a pleasant neutral taste and can be diluted with water to adjust the viscosity and coating effects.

BENEFITS

- Innovative coating effect
- Improved contact time of API to mucosal surfaces
- Improved moisturization and protection
- Pleasant, neutral taste
- Can be diluted with water to adjust viscosity and coating effects

Here's how it works:



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POTENTIAL USES

- Dental/oral rinse/mouthwash
- Swish/spit/swallow formulas
- Oral moisturizer/protectant
- Lip therapy
- Esophageal suspension
- Vaginal conditions
- Enemas
- Rectal conditions
- Wound care
- Nasal

FORMULATED WITHOUT

- Dyes
- Nuts
- Gluten
- Ethanol
- Casein
- Parabens
- Dairy
- Propylene glycol
- Soy
- Flavors



FORMULAS WITH FORMULAPLUS™ BEYOND-USE DATE (BUD) STUDIES

- **PCCA Formula #12228**
Budesonide 1 mg/10 mL to 2 mg/10 mL Oral Suspension (MucoLox) (BUD Bracketed Study)
- **PCCA Formula #11114**
Diazepam 10 mg/Gm Vaginal/Rectal Gel (MucoLox VersaBase®) (BUD Study)
- **PCCA Formula #12238**
Oxytocin 10 Units/0.1 mL to 100 Units/0.1 mL Nasal Spray/Sublingual Suspension (MucoLox) (BUD Bracketed Study)
- **PCCA Formula #14692**
Ketamine 100 mg/mL Nasal Spray (MucoLox) (BUD Study)
- **PCCA Formula #11153**
Lidocaine HCl 10%/Prilocaine HCl 10%/Tetracaine HCl 4% Dental Gel (MucoLox) (BUD Study)

ALSO AVAILABLE

PCCA VersaBase® Gel

- VersaBase Gel is a versatile topical gel base that demonstrates excellent resiliency to low pH (2-7.5) and good compatibility with polar solvents, while maintaining a pleasant, silky feel.
- Easily mixes with equal parts MucoLox in numerous formulations.
- It can be used as a rheology modifier (thickener) or to make surfactant-free gel-creams.

PCCA #30-3656

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FREQUENTLY ASKED QUESTIONS

Can MucoLox be swallowed?

Yes, MucoLox can be swallowed for certain formulas requiring adhesion to the mucosa.

Is MucoLox sugar-free?

MucoLox contains isomalt, an artificial sugar alcohol, which has a low glycemic index and does not promote dental caries.

Can MucoLox be used in animals?

Yes, but it contains sodium benzoate, an ingredient that is potentially toxic to cats on repeated ingestion, so use should be limited in feline patients.

Can MucoLox be sterilized and how?

Yes, in an autoclave.

How can MucoLox be packaged?

Depending on the formulation and dosage form, MucoLox can be packaged in a syringe, tube, oral suspension bottle, metered nasal spray or EMP mixing jar. **Note:** *Packaging thin gels, mouthwashes or oral rinses in an EMP mixing jar may cause leakage; therefore, it is not recommended.*

What gives MucoLox its pleasant, neutral taste?

Isomalt.

Why is MucoLox diluted in the formulas?

Due to the thickness of this base, MucoLox may be diluted with 20-30 percent preserved water. However, diluting reduces the coating effect. If a patient desires more coating, using it at full strength is acceptable.

Why do the mouthwash/oral rinse formulations instruct mixing materials in an EMP mixing jar instead of a beaker with a Spinbar®?

MucoLox is very thick, making it difficult for a Spinbar to thoroughly mix the entire preparation. Instead, it is recommended to mix briskly with a glass stirring rod, transferring to an EMP jar for mixing.

CONTROLLED STUDIES

1. Journal Article: Evaluation of the Safety, Cell Migration and Mucoadhesive Properties of a Mucoadhesive Polymer Blend in Human Oral Mucosa
2. Technical Report: Assessment of the Mucoadhesive Properties of MucoLox Using a 3D Model of the Human Oral Mucosa
3. Technical Report: Evaluation of the Safety and Toxicological Profile of MucoLox: Human Oral Mucosa, Nasal Mucosa and Vaginal Mucosa (3 parts)
 - Technical Report: Evaluation of the Safety and Toxicological Profile of MucoLox: Human Oral Mucosa, Nasal Mucosa and Vaginal Mucosa (Part 1/3)
 - Technical Report: Evaluation of the Safety and Toxicological Profile of MucoLox: Human Oral Mucosa, Nasal Mucosa and Vaginal Mucosa (Part 2/3)
 - Technical Report: Evaluation of the Safety and Toxicological Profile of MucoLox: Human Oral Mucosa, Nasal Mucosa and Vaginal Mucosa (Part 3/3)
4. Scientific Case Study: Chemoradiation Therapy-Induced Oral Mucositis
5. Technical Report: Evaluation of the Safety and Toxicological Profile of Vaginal Gels on a 3D In Vitro Model of the Human Vaginal Mucosa

To see all of our MucoLox studies in depth, visit [PCCA Document #98935](#).

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.