

COMPOUNDING UNIQUE DOSAGE FORMS - RECTAL PREPARATIONS

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INTRODUCTION

- Bryan Ziegler, PharmD/MBA
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 - Clinical Adjunct Associate Professor – Univ. of S. Carolina Coll. Of Pharmacy
- Moss Compounding Pharmacy
 - Full scale compounding pharmacy
 - Human and Veterinary compounding
 - Sterile and Non-sterile
 - Hazardous (Non-sterile only)



WHY USE A COMPOUNDING PHARMACY?

- Opens the door to a wide array of dosage form options
 - Delivering drugs in a different manner than commercially available
 - Great for patients with allergy issues
 - Ideal for dosing options that may not be available
- Allows for a more customized approach to medication treatment
 - The original “personalized medicine”
 - One size does not fit all approach
- Great options in times of drug shortage or discontinuation



DOSAGE FORMS WE'LL COVER

- Suppositories
- Ointments/Creams
- Gels (Mucoadhesive)
- Enemas



COMMON CONDITIONS WE'RE TREATING

- Hemorrhoids
- Fissures
- Proctitis
- Colitis



SUPPOSITORIES

- Internal Options
 - For Hemorrhoids
 - Proctitis
 - Spasms
- Common Formulations:
 - Hydrocortisone 25mg/Pramoxine 10mg suppository
 - SIG: Insert 1 supp PR BID x 7-10 days (Price \$48 for #20)
 - Prednisone suppository (5, 10, or 20mg options)
 - SIG: Insert 1 supp PR QHS x 7 days for proctitis
 - Diazepam 10mg (or 5mg) suppository
 - SIG: Insert 1 supp PR QD PRN rectal spasms



SUPPOSITORIES

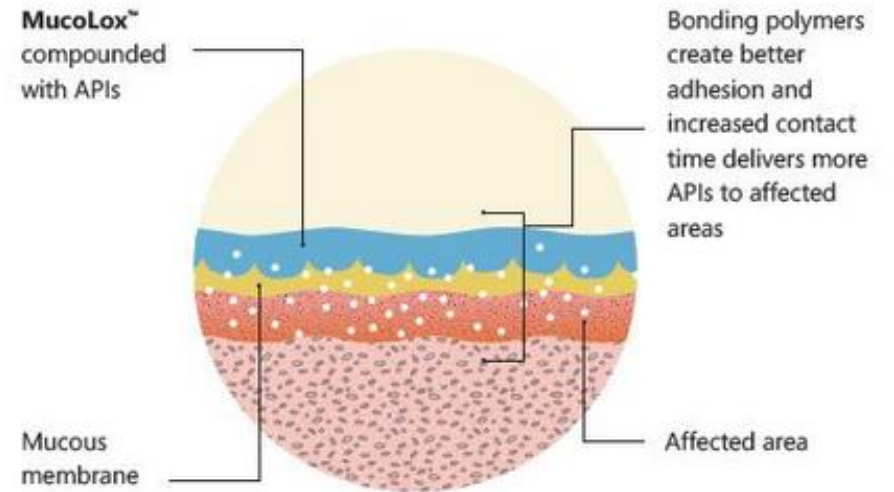
Internal option

- Muco-adhesive options

- Hydrocortisone 30mg Mucolox® Suppositories

- SIG: 1 supp PR BID (Price \$75 for #20)
 - Muco-adhesive polymer incorporated into suppository and creates better adhesion of the active drug to mucosal tissue as suppository melts in the rectum.

Here's how it works:



Source: www.pccarx.com

SUPPOSITORIES

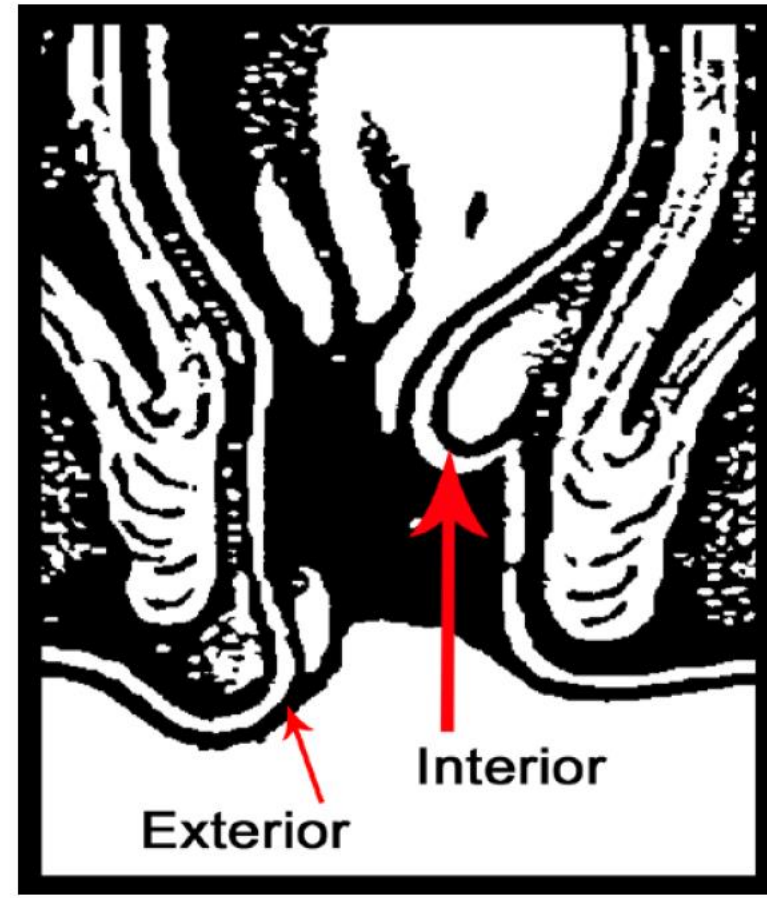
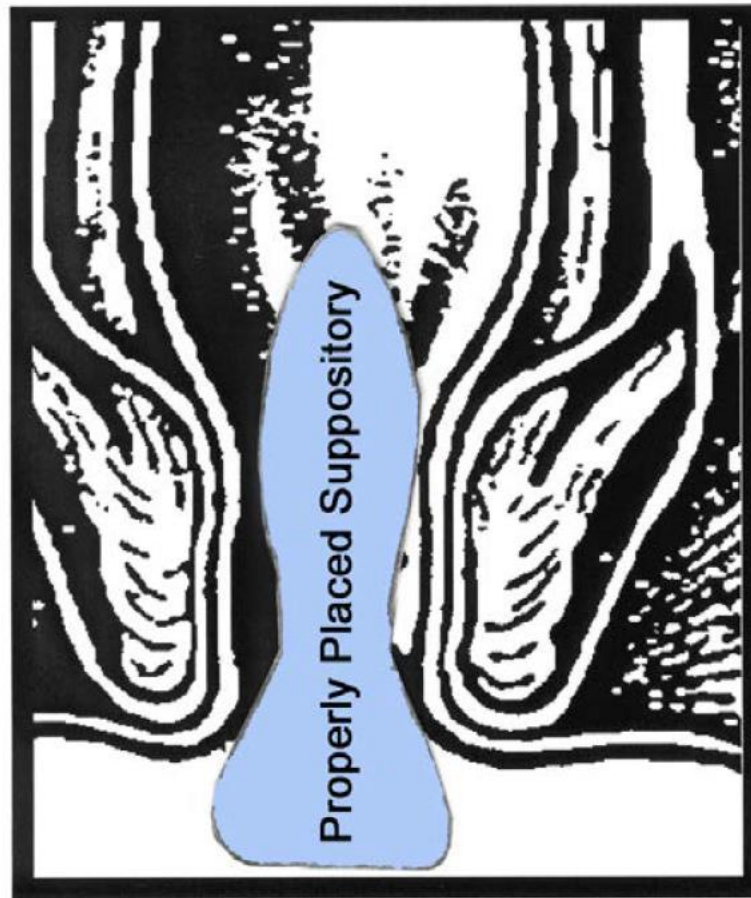
Rectal Rocket Suppository

- Unique shape allows for treatment of internal and external hemorrhoids simultaneously
- Typical formulation =
Hydrocortisone
2.5%/Pramoxine 1%/
Lidocaine 2%
- SIG: 1 PR QHS x 3 nights (for mild to moderate cases)
- Price: \$43 for #3



SUPPOSITORIES

- Rectal Rocket (continued)



GEL

Muco-adhesive Rectal Gel

- Great option for External hemorrhoids
- **Rectal Rocket Gel** (same formula as the suppository)
 - Hydrocortisone 2.5%/Pramoxine 1%/Lidocaine 2%
 - SIG: Apply to affected area BID-TID x 7 days
 - Price: \$45 for 20gm



OINTMENTS/CREAMS

- Typical condition - Fissures
- Common formulations compounded:
 - Nitroglycerin 0.2% in Lanolin
 - Price = \$48/30gm or \$70/60gm
 - Diltiazem 2% ointment
 - Price = \$44/30gm or \$68/60gm
 - Nifedipine 0.2% ointment
 - Price = \$40/30gm or \$55/60gm
 - Typical SIG (for all 3 above): Apply a “pea-size” amount BID
 - Application is peri-anal and/or to anal canal
 - NOTE: Nifedipine may be used up to QID



OINTMENTS/CREAMS

- MOA:

- Nifedipine/Diltiazem – relaxes internal anal sphincter by blocking calcium influx into sphincter smooth muscle cell cytoplasm, reducing spasms and facilitating healing
 - NOTE: muscle contractions can reduce blood flow to the anus and prevent the fissure from healing
- Nitroglycerin - reduction in resting pressure of the internal anal sphincter, which decreases pain and further facilitates healing
 - Also dilates blood vessels and increases blood flow

Source: <https://www.uptodate.com/contents/anal-fissure-beyond-the-basics>



OINTMENTS/CREAMS

- Side Effects
 - NTG ointment - (more common with higher strength and applying too much)
 - Headaches - #1 reason for discontinuation
 - Lightheadedness upon standing
 - Mild burning/tingling sensation
 - Caution in patients with hypotension, utilizing erectile dysfunction meds
 - CCBs (Nifedipine/Diltiazem)
 - Less side effects compared to NTG
 - Caution with hypotension patients
- Several studies have indicated CCBs may be just as effective as NTG ointment, with treatment course lasting 2-6 weeks for most patients.
 - Use has been in acute and chronic fissures

Source: <https://www.pharmacytimes.com/view/anal-fissures-a-real-pain> July 2014;
Patel, Y et al. Treatment of Anal Fissure with Nifedipine/Lidocaine Ointment. *Am J Gastro.* Oct 2004



POTENTIAL ADDITIONS TO OINTMENTS/CREAMS

- Lidocaine 1 – 5%
- Tetracaine 2-4%
- Misoprostol 6.67 mcg/gm



ENEMAS

- Typically used for ulcerative proctitis/colitis or ulcer healing
- Common Formulations:
 - Hydrocortisone 100mg/60mL retention enema
 - SIG: Use QHS x 21 days or until remission
 - Sucralfate 2gm/60mL retention enema
 - SIG: Use daily PRN healing
 - Mesalamine 4gm/60mL retention enema*
 - *When not commercially available



UPCOMING EVENTS

Join us the 4th Tuesday of every month
for new presentations

WHY COMPOUND HORMONES?

TUESDAY, AUGUST 24 @ 6:30 – 7:15 PM



FOR DETAILS - VISIT THE **PRESCRIBER LEARNING CENTER @**
www.mosscompounding.com



QUESTIONS?

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