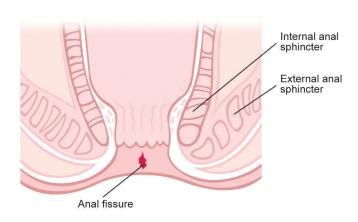
Physician Information Guide

A Clever Solution for Treating Anal Fissure



Eliminate Anal Fissure Pain

Anal fissure pain is caused by internal anal sphincter muscle spasms during a bowel movement. To eliminate fissure pain patients must reduce these spasms by relaxing the internal anal sphincter muscle. Topical medications such as Calcium Channel Blockers (Diltiazem, Nifedipine) or Nitroglycerine (Rectiv) are capable of reducing internal anal sphincter tone and increasing anodermal blood flow^{2,3} thereby affording pain relief and allowing healing of the fissure in many patients⁴.



Intra-Anal Application is Critical

To maximize the effectiveness of these topical medications it is critical to apply them directly to the anal mucosa within the anal canal. This allows the medication to be absorbed more quickly and effectively and provide prolonged relaxation of the sphincter muscle and significant pain relief. Studies have shown that a controlled-dose of topical medication delivered intra-anally produces significantly greater manometric pressure reduction than peri-anal application with a finger¹.

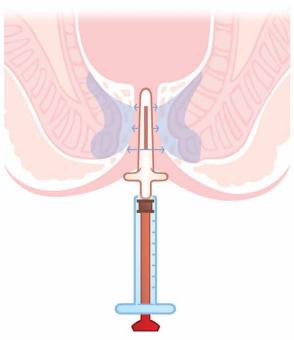
Challenges of Intra-Anal Application

Accurate Delivery to Anal Mucosa

Intra-anal application with a finger is painful, unhygienic and unacceptable for most patients, making patient compliance for a full six-week treatment regimen very difficult¹. Generic rectal applicators are ineffective as they deliver medication into the rectum rather than directly to the anal mucosa within the anal canal.

Accurate Dosing

Most compounded medications are packaged in a tube or jar making it difficult to accurately measure and deliver a precise dose for each use. Patients need a simple and reliable means to accurately measure a single dose from a tube of compounded medication.



Fissure medication delivered to anal mucosa is absorbed by Internal Sphincter Muscle

DoseRite™ is the Solution

DoseRite is a clever solution for the imprecision of self-administered dosing and intra-anal application of compounded topical medication. DoseRite ensures that patients deliver a precise dose of medication directly to the anal mucosa within the anal canal.

DoseRite's single-use applicator was designed by Colorectal surgeons specifically for treating anal fissure¹. The slim profile design eliminates the discomfort of intra-anal application. A closed end with side-slots ensures accurate delivery of medication within the anal canal.

The dosing syringe allows patients to transfer a single dose of medication from their compounded medication tube into the dosing syringe. This simple dosing method improves patient safety and compliance by ensuring a precise dose of medication for each application.

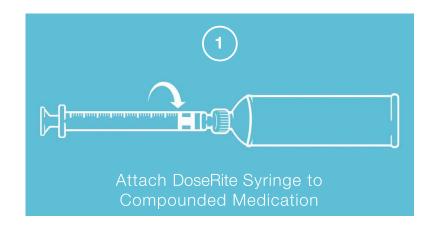
Using DoseRite three times per day will provide prolonged relaxation of the anal sphincter muscle and significant pain relief for a better chance of healing¹.

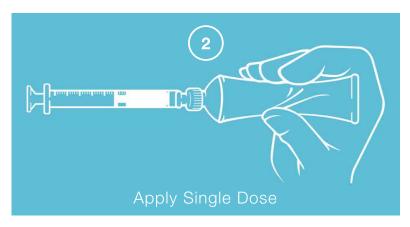
Benefits of DoseRite:

- Direct delivery of medication to anal mucosa for greater manometric pressure reduction of internal sphincter muscles.
- Guarantees the right dose delivered to the right location every time.
- Significantly improves patient compliance.
- Hygienic and portable application of medication.



How Does DoseRite™ Work









How is DoseRite™ Supplied

1 - Physicians receive free DoseRite Trial Packs for their patients by visiting www.doserite.info

The Trial Pack is intended to show patients how precise intra-anal application of topical medication can reduce fissure pain by improving relaxation of the sphincter muscle.

2 - Patients then order a full 6-week pack of DoseRite at Amazon.com

- Cost of 6-week pack (3 doses/day) is \$65.00
- 6-week pack contains the following items:

1 each Universal Tube-to-Syringe Adaptor

6 each Dosing Syringes

126 each Disposable Application Tips



Contents of 6-week Pack

How to Start Your Patients on DoseRite™

- 1. Provide a prescription for a compounded CREAM with an active ingredient (Diltiazem or Nifedipine) or Rectiv (NTG).
 - Medication must be in a **TUBE** format. (all compounding pharmacies offer medication in a tube – you just have to ask).
 - The prescription should be for **90 grams of medication.** (90 grams is required for a 6-week regimen with 3 doses per day.)
 - Dosing Guide we recommend the following dosing :
 - Calcium Channel Blocker
 0.5ml per dose
 - Rectiv (NTG) 0.3ml per dose

(Approximate medication loss with applicator is 0.05ml)

2. Provide the patient with a free DoseRite Trial Pack and Patient Information Guide. (provided with Trial Packs)



Frequently Asked Questions

Why do my patients need DoseRite?

DoseRite reduces the difficulty and inconsistencies of self-administered dosing and intra-anal application of medication. This precise and consistent delivery method improves patient compliance resulting in greater pain relief and happier patients.

Do I have to purchase or sell anything?

No, the patient purchases a 6-week pack from Amazon.com after a successful trial. We also offer a Physician Sales Program for Physicians that want to sell the 6-week DoseRite package.

What's included in a DoseRite Trial Pack?

6 each Disposable Application Tips

1 each Dosing Syringe

1 each Universal Tube-to-Syringe Adaptor

1 each Directions for Use Pamphlet

Are the applicators painful to insert?

No. Patients have commented that insertion of the Application Tips have been simple and pain-free. Patients can use a lubricant like Aquaphor if needed.

How do my patients order the DoseRite 6-week pack?

DoseRite is available for order at Amazon.com. Search for DoseRite directly on Amazon.com or visit the DoseRite website for a direct link to purchase the product.

Is DoseRite reimbursable by insurance?

DoseRite will most likely be an out-of-pocket expense for patients. Most patients agree that the cost (about \$1.50 per day) is acceptable given the amount of relief they experience from this debilitating ailment.

References

- 1. Torabadella L, Salgado G, Controlled Dose Delivery in Topical Treatment of Anal Fissure: Piolot Study of a New Paradigm. Dis Colon Rectum 2005;49: 865-868.
- 2. Schouten WR, Briel JW, Boerma M, et al. Pathophysi- ological aspect and clinical outcome of intra-anal application of isosorbidedinitrate in patients with chronic anal fissure. Gut 1996;39:465–9.
- 3. Farouk R, Duthie GS, MacGregor AB, Bartolo DC. Sustained internal sphincter hypertonia in patients with chronic anal fissure. Dis Colon Rectum 1994;37:424–9.
- 4. Carapeti EA, Kamm MA, Evans BK, Phillips RK. Topical diltiazem and bethanechol decrease anal sphincter pressure without side effects. Gut 1999;45:719–22.
- 5. Antropoli C, Perroti P, Rubino M, et al. Nifedipine for local use in conservative treatment of anal fissures: preliminary results of a multicenter study. Dis Colon Rectum 1999;42:1011–5.
- 6. Madoff R. Pharmacological therapy for anal fissure. N Engl J Med 1998;338:257-9.