

*Are you in pain during and
after a bowel movement?*

**RECTIV can treat the pain
of chronic anal fissure^{1,2}**



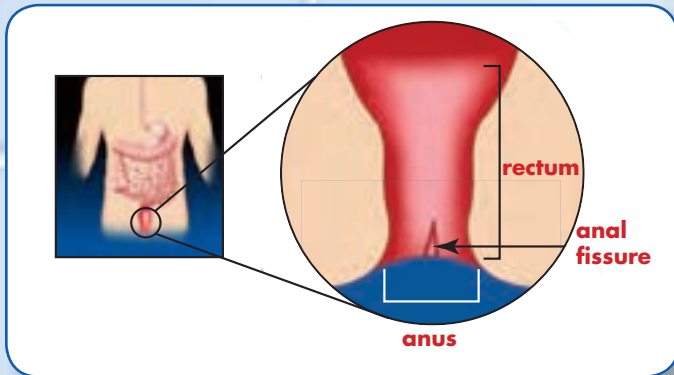
Rectiv[™]
(nitroglycerin) Ointment 0.4%

RECTIV is a prescription medicine used to treat **moderate to severe pain** caused by chronic anal fissures.

Please see additional Important Safety Information throughout and full US Prescribing Information enclosed.

What is an anal fissure?

An **anal fissure** is a cut or tear in the lining of the **anus**. The most common symptoms of an anal fissure are pain and some bleeding, especially during and after a bowel movement. Anal fissures are sometimes confused with hemorrhoids, which may cause pain and bleeding. While an anal fissure is a tear, a hemorrhoid is a swelling either inside or outside of the anus.^{3,4}



What causes anal fissures?

The most common reasons for anal fissures are constipation, hard, dry bowel movements, and other conditions that may cause injury to the anus. Sometimes, frequent diarrhea or other conditions that cause swelling of the anus can cause anal fissures.^{4,5}

Having a bowel movement with an anal fissure can be so painful, some people say it feels like passing razor blades or broken glass.⁶

- RECTIV is not suitable for children and adolescents under the age of 18 years because it has not been studied in this age group

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Talking to your doctor about anal fissure

Many people are embarrassed to talk to their doctor about their chronic anal fissure. But remember, your doctor has treated a lot of people with the same issue. If you think that you have a chronic anal fissure, you can speak to your family doctor or to a specialist who treats diseases of the digestive system, such as a gastroenterologist or a colorectal surgeon.

Anal fissure is more common than you might think:

Nearly 400,000 people a year in the US are diagnosed with anal fissure.^{2,7,8}

Important Safety Information

- Do not use RECTIV if you:
 - Are taking a medicine for erectile dysfunction (male impotence), such as Viagra® (sildenafil), Cialis® (tadalafil), or Levitra® (vardenafil), or for pulmonary hypertension. If you have questions, consult your pharmacist or health care provider
 - Have been told by your doctor that you have severe anemia (low numbers of red blood cells)
 - Have increased intracranial pressure or high pressure within your skull (eg, following a head injury or bleeding in your brain)
 - Are allergic to any of the ingredients in RECTIV, or have had an allergic reaction to similar medications in the past

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When anal fissures become chronic

When anal fissures do not heal with diet or lifestyle changes (see next page), they may become chronic, which means that they stay for a long time. While anal fissure pain may sometimes go away on its own, if it becomes chronic, your doctor may suggest that you use a prescription medicine for the pain.⁴

What to expect when you visit your doctor

Your doctor will first talk to you about what kind of pain you are having. He or she will then examine the outside of your anus to see if you have the signs of a chronic anal fissure. Rarely, if it is not too painful for you, your doctor will put a gloved finger inside your **rectum**—the area between the colon and the anus—to examine it.^{9,10}

Important Safety Information

- Tell your doctor about all of your medical conditions including if you:
 - Have low blood pressure
 - Have recently had a heart attack
 - Have heart or blood vessel disorders
 - Suffer from migraines or recurrent headaches
 - Are pregnant or plan to become pregnant
 - Are breastfeeding or plan to breastfeed
 - It is not known if RECTIV will harm your unborn baby or if the components of RECTIV will harm your child if you breastfeed
- RECTIV may lower your blood pressure. When getting up from a lying or sitting position, you should get up slowly, otherwise you might faint
- Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Tell your doctor if you are taking other products that contain nitroglycerin, medicine for erectile dysfunction, certain medicines used for pulmonary hypertension, medicine used to treat high blood pressure, aspirin, ergotamine (used to treat migraine), tissue-type plasminogen activator (used to help dissolve blood clots in the heart, lungs, and brain), or are to be given heparin

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Managing chronic anal fissure

Lifestyle changes

If your chronic anal fissure was caused by constipation or hard stools, you can add fiber to your diet to make your bowel movements more regular. This can be done by eating more fiber-rich foods or by taking fiber supplements or stool softeners. If you increase your fiber intake, be sure to drink more fluids, such as water. Some people also find that warm baths—which can relax the anal muscles—can help relieve chronic anal fissures.⁴

Fiber-rich foods¹¹:

Bran cereals	Fruit	Nuts and seeds
Beans	Vegetables	Whole grains

Medication to treat the pain of chronic anal fissure

Your doctor may also have you try a prescription medicine, such as a nitroglycerin (NYE-troe-GLIS-er-in) ointment.⁵ In fact, one of the leading physician groups for treating patients with chronic anal fissure—the American Society of Colon and Rectal Surgeons—recommends using nitroglycerin ointment to treat pain from chronic anal fissure.¹²

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RECTIV—for the treatment of moderate to severe pain from chronic anal fissure

RECTIV, a nitroglycerin ointment, is the first and only US Food and Drug Administration (FDA)–approved medicine for the treatment of moderate to severe pain from chronic anal fissure. In clinical studies, RECTIV was found to be effective in treating pain from chronic anal fissure.^{1,2}

One common side effect of RECTIV is headache. However, this type of headache usually doesn't last very long and can be treated with an over-the-counter medicine, such as Tylenol® (acetaminophen). If the headaches are severe, you may need to ask your doctor whether you should stop using RECTIV. RECTIV causes dose-related headaches, which may be severe, but as you get used to RECTIV, they may become less severe.¹

Important Safety Information

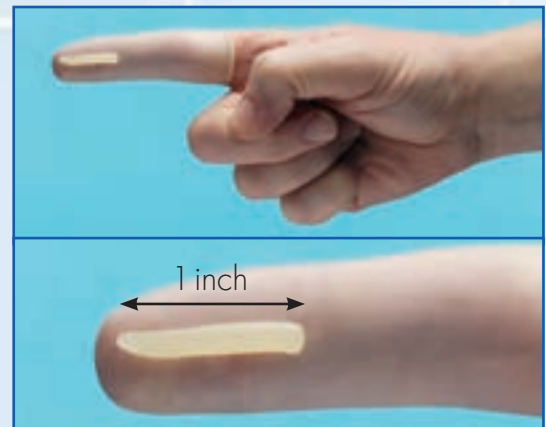
- Do not drive or operate machinery immediately after applying RECTIV. If you feel dizzy or light-headed after applying the ointment, do not drive or operate machinery until the dizziness has stopped
- Avoid consuming alcohol while you are using RECTIV, as your blood pressure is more likely to be affected if you consume alcoholic beverages
- RECTIV can cause serious allergic reactions, including swelling of the face, lips, tongue, or throat, or difficulty breathing. If you have an allergic reaction, stop using RECTIV and seek immediate medical attention

References: **1.** RECTIV US Prescribing Information; June 2011. **2.** Data on file. Aptalis Pharma US, Inc. **3.** Hemorrhoids and other anal disorders. American College of Gastroenterology Web site. <http://patients.gi.org/topics/hemorrhoids-and-other-anal-disorders>. Accessed January 30, 2012. **4.** Anal fissure. American Society of Colon & Rectal Surgeons Web site. http://www.fascrs.org/patients/conditions/anal_fissure. Accessed January 30, 2012. **5.** Villalba H, Villalba S, Abbas MA. Anal fissure: a common cause of anal pain. *Perm J.* 2007;11(4):62-65. **6.** Altomare DF, Binda GA, Canuti S, Landolfi V, Trompetto M, Villani RD. The management of patients with primary chronic anal fissure: a position paper. *Tech Coloproctol.* 2011;15(2):135-141. **7.** Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report.* 2009;11:1-28. **8.** Cross KLR, Massey EJD, Fowler AL, Monson JRT. The management of anal fissure: ACPGBI position statement. *Colorectal Dis.* 2008;10(Suppl 3):1-7. **9.** US National Library of Medicine, National Institutes of Health. Anal fissure. <http://www.nlm.nih.gov/medlineplus/ency/article/001130.htm>. Updated September 21, 2010. Accessed January 30, 2012. **10.** US National Library of Medicine, National Institutes of Health. Digital rectal exam. <http://www.nlm.nih.gov/medlineplus/ency/article/007069.htm>. Updated February 2, 2011. Accessed January 30, 2012. **11.** Palmer S. The top fiber-rich foods list. *Today's Dietitian.* 2008;10(7):28. <http://www.todaysdietitian.com/newarchives/063008p28.shtml>. Accessed January 30, 2012. **12.** Perry WB, Dykes SL, Buie WD, Rafferty JF; Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for the management of anal fissures (3rd revision). *Dis Colon Rectum.* 2010;53(8):1110-1115.

Please see additional Important Safety Information throughout and full US Prescribing Information enclosed.

How to use RECTIV¹

- Apply the ointment every 12 hours exactly as your doctor has told you to
- Cover your finger with plastic wrap, a disposable surgical glove, or a finger cot
- Lay the covered finger alongside the 1-inch dosing line marked on the side of the medicine box so that the tip of your finger is at one end of the dosing line —Refer to carton for accurate dosage guide
- Starting at the tip of the finger, squeeze the ointment onto your finger so it is the same length as what is marked on the box



- Gently insert the finger with the ointment into the anal canal, up to the first finger joint
- Carefully smear the ointment around the inner sides of the anal canal. If this cannot be achieved due to pain, apply the ointment directly to the outside of the anus
- When you are done, throw the finger covering into the garbage, out of the reach of children and pets. Remember to wash your hands

Follow your doctor's instructions about how often and how long to use RECTIV

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When chronic anal fissure strikes,
RECTIV treats the pain



RECTIV is a prescription
medicine used to treat
moderate to severe pain
caused by chronic anal fissures.

Important Safety Information

- The most common side effects of RECTIV are:
 - Headaches, which can be severe. If you have a headache, you may take over-the-counter painkillers (such as acetaminophen), or ask your doctor whether you should stop taking RECTIV
 - Dizziness, faintness on standing, or light-headedness

These are not all the possible side effects of RECTIV. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

KEEP RECTIV OUT OF THE REACH OF CHILDREN.

Please see additional Important Safety Information throughout and full US Prescribing Information enclosed.

APTALIS[™]

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