

DILTIAZEM TOPICAL CREAM

Benefits

- Diltiazem cream is used to promote the healing and reduce symptoms of an anal fissure. An anal fissure is a tear in the skin of the lower half of the anal canal (back passage). Symptoms can include severe and sharp pain, irritation and tenderness. Certain fissures may heal quite quickly, whereas others can take several months to heal.
 - Doctors may prescribe medications for off-label use, meaning the FDA has not approved the medication to treat that specific condition. Ask your pharmacist or physician if you have any questions regarding the use of your medication.
- The amount of time it takes to see the full effects of the medication varies between each patient. Consult your prescriber for additional information.

Side Effects

- All medicines have potential side effects which may or may not occur in people who take them. The most common side effects reported by people who use diltiazem hydrochloride cream (which occur in less than one out of every 10 people) are:
- Headaches – these will usually be mild. If the headache does not resolve or is unpleasant, please consult your pharmacist or doctor.
- Light-headedness or dizziness, especially when getting up from a sitting or lying down position. If you begin to feel dizzy, sit or lie down until the feeling passes.
- Local itching, soreness or rectal bleeding. Severe side effects are rare but may occur.
 - If you experience a severe side effect while taking this medication, please call your physician immediately. You may also report the side effect to the FDA Med-Watch Program at 1-800-FDA-1088.

Administration

- Wash your hands before and after you use the cream to ensure hygiene is maintained.
- Apply the amount of cream specified on the prescription label, to your finger.
- Apply the cream just inside and around the anus (back passage) as instructed by your doctor. A finger covering such as cling film, disposable glove or finger cot may be used to apply the cream (you can get finger coats from a local pharmacy or surgical supplies retailer).
- Use the cream twice daily (morning and evening) or as directed by your doctor. •
- Try to ensure you have opened your bowels before using the cream. This is so that the cream can be in contact with the rectal tissue for as long as possible.

Duty to Warn for Topical Medications

It is possible for topical medications to be transferred on to other individuals through casual contact which can lead to unwanted side effects in those individuals. To prevent their



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exposure, don't allow skin-to-skin contact of the treated area with other adults, children or pets. Keep the treated area covered with loose fitting clothing or lightly wrapped gauze until the drug is completely absorbed, which can take up to 4 hours.

Hand washing does not remove all the drug residue from your skin. It is best to apply medication with a disposable glove. Ask your pharmacist about any questions or concerns you might have.

Description

- If cream changes color or separates. Pause use and contact the pharmacy at 734-545-1117 extension 0 and ask to speak to a representative.

Additional Information/Warnings

- If you miss a dose of this medication, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once. If you have any questions, please contact your physician or pharmacist.
- Before taking this medication, tell your healthcare provider about all the medications you are currently taking including prescription medications, herbal supplements, vitamins, and over-the-counter medications.
- Call your doctor immediately if you are pregnant, intend to become pregnant, or intend to breastfeed. Your doctor will need to review each medication used during pregnancy or breastfeeding.
- Continue to have routine appointments with your physician in order to assess and monitor your response to the medication and condition as recommended.
- Do not share medication with another person, even if they have the same symptoms you are experiencing.
- The information in this patient advisory leaflet is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. If you have questions about the medicines, you are taking or would like more information, check with your doctor or pharmacist.
- This compound medication is customized for the patient and is exclusively available with the prescription from a prescriber.
- Please refer to receipt for a list of ingredients in your medication.

Storage

- Refer to the label on your prescription for refrigeration requirements (do not freeze).



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- If refrigeration is NOT required- store medication at room temperature in a cool, dry place. Do not store it in the bathroom, a vehicle, or any other location with varying temperatures or humidity.
- If refrigeration is required store in the refrigerator out of reach of children.
- Compounded medications are not usually prepared in child resistant containers and should be kept away from children and pets. If you would like to have a lockable zip lock bag for your compounded medications, please call the pharmacy and ask the technician to include child resistant packaging with your refills.
- Unused medications left in the medicine cabinet can be a temptation for children and teenagers. Discard unused medications promptly. Do not flush drugs down the toilet or into the sink drain as they could be hazardous to the environment. Contact your local disposal company for more details about how to safely discard medications when they are expired or no longer needed. Big Red Barrel and Yellow Jug are national drug disposal programs. Visit www.bigredbarrel.com
- Contamination may occur if the closed container device is tampered with. Do not open the device. It is designed to deliver the correct dose when used properly.

Prescription Expiration & Medication Beyond Use Date

- Refer to the label for the expiration date of your prescription.
 - Your prescription expires in two ways:
 - You have used all the refills prescribed.
 - The prescription has reached the expiration date of one year (or six months for controlled drugs).
 - When a prescription expires, allow plenty of time to visit your doctor and for the pharmacist to compound your prescription renewal.
- Refer to the *discard date* or *beyond use date* on your bottle to learn when your medication should be discarded. Compounded medications have a shorter shelf life than those of manufactured drugs. The beyond use date is the longest date we can guarantee full potency of your medication.

Please contact Valiant Compounding Pharmacy at 734-545-1117 or toll free at 855-466-2583 with any questions, concerns, or for prescription refills.



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