

Guidance for the use of Diltiazem 2% cream/ointment in the management of anal fissures

This guidance was initially drafted by Gillian Smith (Medicines Information Pharmacist) in consultation with Mr J Bannister, Mr T Offori and Miss A Payne (Consultant Colorectal Surgeons) to support all physicians managing a patient who is prescribed diltiazem cream/ointment.

Diltiazem 2% cream/ointment is an unlicensed special preparation and any doctor who prescribes the medication legally assumes clinical responsibility for the drug, and the consequences of its use.

Barnsley Hospital will prescribe diltiazem 2% cream. However in primary care diltiazem 2% ointment should be prescribed as this is the most cost-effective formulation. The cream and ointment can be used interchangeably.

Introduction:

Diltiazem is a benzothiazepine calcium channel blocker, used topically to affect smooth muscle relaxation of the internal anal sphincter.

Topical diltiazem 2% may be used in the management of anal fissures unresponsive to first line pharmacological treatments (such as topical GTN ointment), or where these treatments are not tolerated by the patient.

Cautions, Contraindications and Drug Interactions:

The use of diltiazem topically is associated with minimal absorption and subsequently low drug concentrations in the systemic circulation. However, it would be prudent to use cautiously in any patient with cautions or contraindications for the use of oral diltiazem, such as those with bradycardia or heart block, or with LVF associated with pulmonary congestion.

Drug interactions with oral diltiazem are listed in the BNF, although due to the low absorption when used topically, significant interactions with topical diltiazem 2% are not expected.

Dosage, administration and treatment duration:

Topical Diltiazem 2% should be applied twice a day for a maximum of 6 weeks. If healing of the fissure has not been achieved following 6 weeks of treatment, then colorectal surgical referral is advised for further assessment, including a decision as to whether a second course of treatment is reasonable, or whether surgery is indicated.

Adverse effects:

Mild headache, perianal itching and contact dermatitis has sometimes been noted with topical diltiazem preparations. Other side effects associated with systemic treatment are listed in the BNF.

Pregnancy and Lactation:

There is limited information on the use of diltiazem during pregnancy, please contact medicines information directly for case-specific information to be given.

Systemic diltiazem is well tolerated during breast feeding and hence no concerns regarding use of the topical cream in these circumstances. If there are other clinical issues with either mum or baby, please contact medicines information for more individualised information.

Immediate advice and support:

Contact Detail	Telephone No.	E-mail
Gillian Turrell – Lead Pharmacist Medicines Information	01226 432857	gilliansmith2@nhs.net
Miss A Payne - Consultant Colorectal Surgeon	01226 430000	alisonpayne@nhs.net
Mr. Christopher Whitfield - Consultant Colorectal Surgeon	01226 430000	christopherwhitfield@nhs.net

References:

1. BNF number 76 accessed online via www.bnf.org
2. Martindale: The Complete Drug Reference, accessed online via www.medicinescomplete.com
3. Schaefer C et al (eds). *Drugs during Pregnancy and Breastfeeding* 3rd Ed. Published by Academic Press.
4. NICE ESUOM03 Chronic anal fissure: 2% topical diltiazem hydrochloride 2013

This document was originally produced by BHNFT in October 2012 and updated in January 2016, November 2018 and March 2021. It was approved at the APC on 12th May 2021.