

LABELLING STANDARD - ANORECTAL DRUG PRODUCTS

1. DEFINITION:

A topical or intrarectal nonprescription drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

NOTE: In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

2. MEDICINAL INGREDIENTS and CONCENTRATIONS:

All finished product and ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this standard consist of the following ingredients when used singly or in acceptable combinations within the established limits given:

2.1 Local Anesthetics

a)	benzocaine	5 - 20%
b)	benzyl alcohol	1 - 4%
c)	dibucaine (hydrochloride)	0.25 - 1%
d)	dyclonine hydrochloride	0.5 - 1%
e)	lidocaine	2 - 5%
f)	pramoxine hydrochloride	1%
g)	tetracaine (hydrochloride)	0.5 - 1%

2.2 Vasoconstrictor

a)	ephedrine sulfate	0.1 - 1.25%
b)	epinephrine (hydrochloride)	0.005 - .01%
c)	phenylephrine hydrochloride	0.25%

2.3 Protectant

- the following may be used as a single ingredient in a product if it comprises 50% or more by weight of the final product
- the following may be used in combinations in accordance with **3.1**
 - a) aluminum hydroxide gel
 - b) cocoa butter
 - c) glycerin in a 20 - 45% (w/w) aqueous solution
 - d) kaolin
 - e) lanolin
 - f) mineral oil
 - g) petrolatum
 - h) topical starch
 - i) white petrolatum

- the following may not be used as a sole protectant ingredient but may be used in combination with other protectant ingredients in accordance with 3.1
- a) calamine (not to exceed 25% by weight per dosage unit - based on the zinc oxide content of calamine)
- b) cod liver oil
- c) shark liver oil
- d) zinc oxide (not to exceed 25% by weight per dosage unit)

2.4 Analgesic, Anesthetic, Antipruritic

- a) camphor 0.1 - 3%
- b) juniper tar 1 - 5%
- c) menthol 0.1 - 1%

2.5 Astringent

- a) calamine, within a concentration of 5-25% by weight per dosage unit (based on the zinc oxide content of calamine)
- b) hamamelis water, NF XI, 10-50%
- c) zinc oxide 5-25% by weight per dosage unit

2.6 Keratolytic

- a) alcloxa 0.2 - 2%
- b) resorcinol 1 - 3%

3. **PERMITTED COMBINATIONS**

- 3.1 Any two, three of four protectants identified in 2.3 may be combined provided the combined percentage (by weight) is at least 50% of the final product (eg. 1g of a 2g dosage unit). Any protectant included in the combination must be present at a level that contributes at least 12.5% by weight (eg. 0.25g of a 2g dosage unit), except cod liver oil and shark liver oil.
- 3.2 Any single anorectal ingredient identified in 2.1, 2.2., 2.4, 2.5 and 2.6 may be combined with up to four protectants in accordance with 3.1
- 3.3 Any single local anesthetic (2.1) with any single vasoconstrictor (2.2)
- 3.4 Any single local anesthetic (2.1) with any single astringent (2.5)
- 3.5 Any single local anesthetic (2.1) with any single keratolytic (2.6)
- 3.6 Any vasoconstrictor (2.2) with any single astringent (2.5)
- 3.7 Any single analgesic, anesthetic, antipruritic (2.4) with any single astringent (2.5)
- 3.8 Any single analgesic, anesthetic and antipruritic (2.4) with any single keratolytic (2.6)
- 3.9 Any single astringent (2.5) with any single keratolytic (2.6)

- 3.10 Any single local anesthetic (2.1) with any single vasoconstrictor (2.2)
- 3.11 Any single local anesthetic (2.1) with any single astringent (2.5) and with any single keratolytic (2.6)
- 3.12 Any single vasoconstrictor (2.2) with any single analgesic, anesthetic and antipruritic (2.4) and with any single astringent (2.5)
- 3.13 Any single analgesic, anesthetic and antipruritic (2.4) with any single astringent (2.5) and with any single keratolytic (2.6)
- 3.14 Any combination of ingredients listed in 3.3 - 3.13 of this section with up to four protectants in accordance with 3.1
- 3.15 Any product containing calamine for use as a protectant and/or as an astringent and/or containing zinc oxide for use as a protectant and/or as an astringent may not have a total weight of zinc oxide exceeding 25% by weight per dosage unit.

4. **INDICATIONS**

4.1 General

- for the temporary relief (helps relieve the) discomfort and/or itching in the perianal area (or associated with) hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues, anorectal inflammation, hemorrhoidal tissues or piles.

4.2 Local Anesthetics

- for the temporary relief of pain, soreness or burning

4.3 Vasoconstrictor

- temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders.
- temporarily shrinks hemorrhoidal tissue.

4.4 Protectant

For products containing ingredients identified in 2.3b, c, e-i:

- temporarily forms a protective coating over inflamed tissues to help prevent drying of tissues
- temporarily protects irritated areas
- temporarily relieves burning
- provides temporary relief from skin irritations
- temporarily provides a coating for relief of anorectal discomforts

- temporarily protects the inflamed, irritated anorectal surface: to help make bowel movements less painful from irritation and abrasion during bowel movement
- temporarily protects inflamed perianal skin
- temporarily relieves the symptoms of perianal skin irritation

For aluminum hydroxide gel (2.3a) and Kaolin (2.3d)

- for the temporarily relief of itching associated with moist anorectal conditions.

4.5 Analgesic, Anesthetic, Antipruritic

- for the temporarily relief of pain or burning
- can help distract from pain
- may provide a cooling sensation

4.6 Astringent

- aids in protecting irritated anorectal areas
- temporarily relief of irritation or burning

4.7 Keratolytic

- see 4.1

5. DIRECTIONS FOR USE

5.1 General

- a) Adult: Cleanse the affected area with: mild soap and warm water and rinse thoroughly/by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- b) children under 12 years of age: consult a physician
- c) apply externally to the affected area
- d) gently apply to the affected area by patting and then discard (pad)

5.2 Intrarectal use

- a) remove wrapper before inserting into the rectum (wrapped suppositories)
- b) FOR INTRARECTAL USE: Attach applicator to tube, lubricate applicator well, then gently insert applicator into the rectum

5.3 Local Anesthetic

For 2.1a, b, d, e, g: apply to the affected area up to 6 times daily.

For dibucaine (hydrochloride): apply to the affected area up to 3 to 4 times daily

For pramoxine hydrochloride: apply to the affected area up to 5 times daily

5.4 Analgesics, Anesthetics, Antipruritics

- apply to the affected area up to 6 times daily

5.5 Keratolytics

- as per 5.4

5.6 Vasoconstrictors

- apply to the affected area up to 4 times daily

5.7 Protectants (except petrolatum) Astringents

- apply to the affected area up to 6 times daily or after each bowel movement (Petrolatum/white petrolatum-apply liberally to the affected area as often as necessary.)

6. **WARNINGS**

6.1 General

- a) if condition worsens or does not improve within 7 days, consult a physician;
- b) do not exceed the recommended daily dosage, unless directed by a physician;
- c) in case of bleeding, consult a physician promptly;
- d) do not put this product into the rectum by using fingers or any mechanical device or applicator (for products for external use only).

6.2 Intrarectal Use Products

- do not use this product with an applicator if the introduction of the applicator into the rectum causes additional pain. Consult a physician promptly.

6.3 Local Anesthetics\Menthol\Resorcinol

- certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a physician.

6.4 Vasoconstrictor

- do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a physician
- do not take this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your physician.

For ephedrine sulfate:

- some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your physician.

6.5 Protectants

For aluminum hydrochloride gel (2.3a) and kaolin (2.3d)

- remove petrolatum or greasy ointment before using this product because they interfere with the ability of this product to adhere properly to the skin area.

6.6 Keratolytic

For resorcinol (2.6b):

- do not use on open wounds near the anus.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

Bureau of Nonprescription Drugs
revised: September 1, 1994

REFERENCES:

United States Department of Health and Human Services, Food and Drug Administration, Federal Register, Anorectal Drug Products for Over-the-Counter Use; Tentative Final Monograph; Notice of Proposed Rulemaking, Vol. 53, No. 157, 1988, pp. 30756-30784.