AnaMantle HC advertisement.

[s.l.]: [s.n.], 2003

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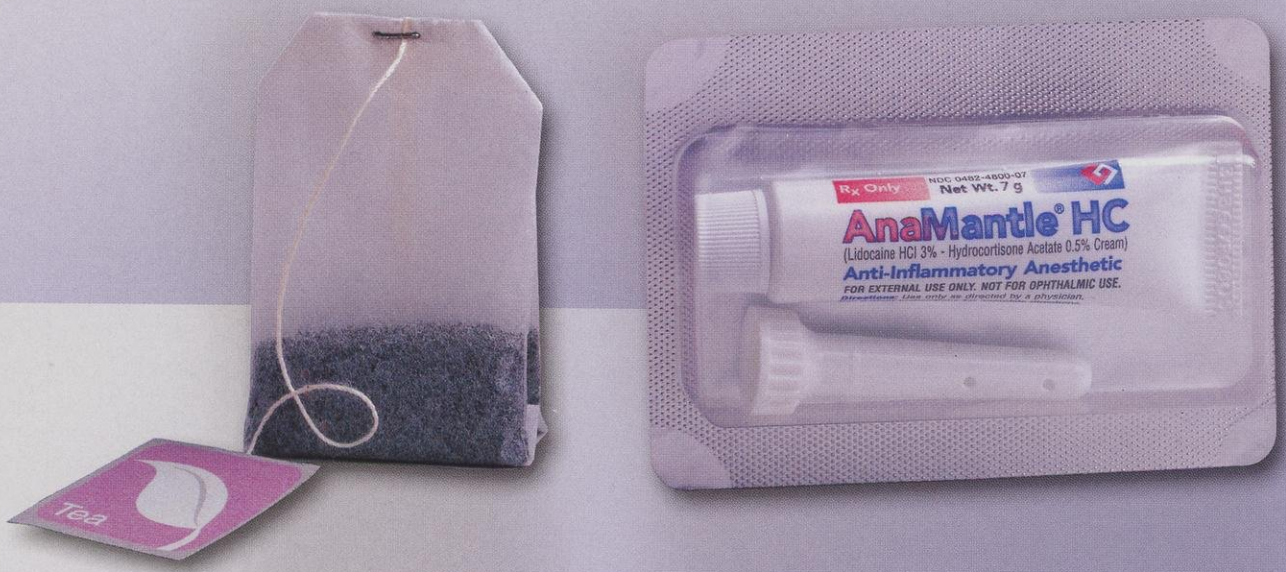
Some Things Are Made To Be Single Use.



Rx Only

AnaMantle® HC

(Lidocaine HCl 3% - Hydrocortisone Acetate 0.5%) Cream

Single-Use Hemorrhoid Treatment

- Convenient, Clean
- Use Once, Then Dispose
- **AnaMantle® HC Kit** contains 14 single-use tubes with disposable applicators

Effective ingredients

Rx
AnaMantle® HC Kit
sig: BID (morning and evening) for 7 days

Please see Prescribing Information

KENWOOD THERAPEUTICS
A DIVISION OF BRADLEY PHARMACEUTICALS, INC.
383 Route 46 West • Fairfield, NJ 07004-2402
1-800-929-9300 • www.bradpharm.com

Rx Only

AnaMantle® HC

(Lidocaine HCl 3% - Hydrocortisone Acetate 0.5% Cream)

INDICATIONS: **AnaMantle® HC** is used for the anti-inflammatory and anesthetic relief of itching, pain, soreness and discomfort due to hemorrhoids, anal fissures, pruritus ani and similar conditions of the anal area.

CONTRAINDICATIONS: **AnaMantle® HC** should not be used in patients with a history of sensitivity to any of its ingredients or adverse reactions to lidocaine or amide anesthetics, which usually do not cross-react with "caine" ester type anesthetics. If excessive irritation and significant worsening occur, discontinue use and seek the advice of your physician. **AnaMantle® HC** and topical lidocaine should be used cautiously in those with impaired liver function, as well as the very ill or very elderly and those with significant liver disease. **AnaMantle® HC** should be used with caution in patients receiving antiarrhythmic drugs of Class I since the adverse effects are additive and generally synergistic. **AnaMantle® HC** is contraindicated for tuberculous or fungal lesions or skin vaccinia, varicella and acute herpes simplex. Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS: For external use only. Not for ophthalmic use. Product and used applicators could harm small children if chewed or swallowed. Individual tubes are NOT child resistant. Keep the product inside the child resistant blister until ready to use.

Keep product and used applicators out of the reach of children.

Topical formulations of lidocaine may be absorbed to a greater extent through mucous membranes and abraded, fissured or irritated skin than through intact skin. **AnaMantle® HC** should not be ingested or applied into the mouth, inside of the nose or in the eyes. **AnaMantle® HC** should not be used in the ears. Any situation where lidocaine penetrates beyond the tympanic membrane into the middle ear is contraindicated because of ototoxicity associated with lidocaine observed in animals when instilled in the middle ear. **AnaMantle® HC** should not come into contact with the eye or be applied into the eye because of the risk of severe eye irritation and the loss of eye surface sensation which reduces protective reflexes and can lead to corneal irritation and possibly abrasion. If eye contact occurs, rinse out the eye immediately with saline or water and protect the eye surface until sensation is restored.

PRECAUTIONS: If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. If extensive areas are treated, the possibility of systemic absorption exists. Systemic absorption of topical steroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glycosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of potent topical steroids applied to a large surface area, or under an occlusive dressing, should be evaluated periodically for evidence of HPA axis suppression. If noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of the HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionately larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. If irritation develops, topical steroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Carcinogenesis, Mutagenesis, And Impairment Of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Studies of lidocaine in animals to evaluate the carcinogenic and mutagenic potential of the effect on fertility have not been conducted.

Use In Pregnancy: Teratogenic Effects: Pregnancy Category B Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering lidocaine to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to a nursing mother.

Pediatric Use: Safety and efficacy in children have not been established.

ADVERSE REACTIONS: During or immediately following application of **AnaMantle® HC**, there may be transient stinging or burning from open areas of skin, or transient blanching (lightening), or erythema (redness) of the skin.

DOSAGE AND ADMINISTRATION: Apply **AnaMantle® HC** to the affected area(s) twice daily or as directed by a physician. The cap should be removed from the tube of **AnaMantle® HC** and the applicator tip firmly screwed onto the end of the tube and tightened. While holding the tube, squeeze the tube to fill the applicator until a small amount of cream shows and lubricate the end of the tip with cream. Gently insert the applicator tip with attached tube into anal area. Continue squeezing the body of the tube as it is moved around the areas of discomfort, and lastly, around and in the anal opening (if directed by physician).

Do not completely insert the applicator and tube into the anus or insert deep into the rectum. Do not insert a loose applicator tip into the anus or rectum. Once application is completed, the tube and applicator tip should be gently removed from the area and disposed. Note that an adequate amount of **AnaMantle® HC** for an application to the anal and peri-anal area will be applied through the applicator tip by gently squeezing the tube during application. **AnaMantle® HC** should not be used in excess of recommendations or for prolonged use in the anal canal. If the condition does not respond to repeated courses of **AnaMantle® HC**, or should worsen, discontinue use and seek the advice of your physician.

HOW SUPPLIED:

AnaMantle® HC Kit – NDC 0482-4800-14 contains 14 tubes, 1/4 oz. (7 g) each, and 14 single-use applicators.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Store at controlled room temperature 15°-30° C (59°-86° F).

Protect from freezing.

Manufactured for:

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www.bradpharm.com

Manufactured by:
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Montreal, QC H4S 1X6 CANADA

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