Food and Drug Administration, HHS

§ 346.10 Local anesthetic active ingredients.

The active ingredient of the product consists of any of the following when used in the concentration or within the conditions established in this part and each general condition established in §330.1 of this chapter.

(a) Analgesic, anesthetic drug. A topically (externally) applied drug that relieves pain by depressing cutaneous sensory receptors.

(b) Anorectal drug. A drug that is used to relieve symptoms caused by anorectal disorders in the anal canal, perianal area, and/or the lower rectal areas.

(c) Antipruritic drug. A topically (externally) applied drug that relieves itching by depressing cutaneous sensory receptors.

(d) Astringent drug. A drug that is applied topically (externally) to the skin or mucous membranes for a local and limited protein coagulant effect.

(e) External use. Topical application of an anorectal drug product to the skin of the perianal area and/or the skin of the anal canal.

(f) Intrarectal use. Topical application of an anorectal drug product to the mucous membrane of the rectum.

(g) Keratolytic drug. A drug that causes desquamation (loosening) and debridement or sloughing of the surface cells of the epidermis.

(h) Local anesthetic drug. A drug that produces local disappearance of pain, burning, itching, irritation, and/or discomfort by reversibly blocking nerve conduction when applied to nerve tissue in appropriate concentrations.

(i) Protectant drug. A drug that provides a physical barrier, forming a protective coating over skin or mucous membranes.

(j) Vasconstrictor. A drug that causes temporary constriction of blood vessels.