HYDROCORTISONE ACETATE PRAMOXINE HYDROCHLORIDE- hydrocortisone acetate and pramoxine hydrochloride suppository
Pageview Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

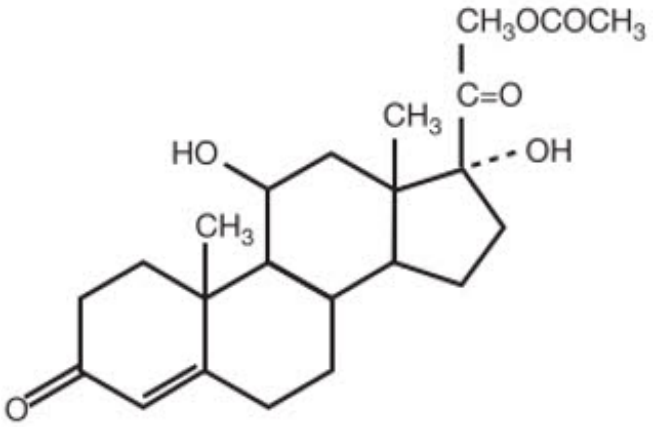
Hydrocortisone Acetate 25 mg and Pramoxine Hydrochloride 18 mg Suppositories

For Rectal Administration

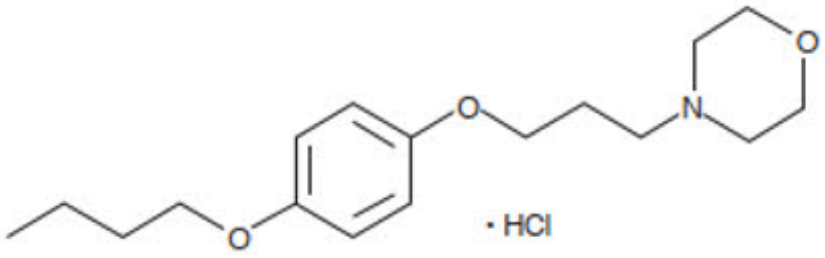
Rx Only

DESCRIPTION

Hydrocortisone acetate is a corticosteroid designed chemically as pregn-4-ene 3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy–(11b) with the following structural formula:



Pramoxine Hydrochloride is a topical anesthetic agent designed chemically as 4-(3-(butoxyphenoxy)propyl)morpholine hydrochoride with the following structural formula:



Each suppository for rectal administration contains hydrocortisone acetate, USP 25 mg and pramoxine hydrochloride, USP 18 mg in a specially blended hydrogenated vegetable base.

CLINICAL PHARMACOLOGY

In normal subjects, about 26% of hydrocortisone acetate is absorbed when the suppository is applied to the rectum. Absorption of hydrocortisone acetate may vary

across abraded or inflamed surfaces.

Topical steroids are primarily effective because of their anti-inflammatory, anti-pruritic and vasoconstrictive action.

Pramoxine hydrochloride is a topical anesthetic agent which provides temporary relief from itching and pain. It acts by stabilizing the neuronal membrane of nerve endings with which it comes into contact.

INDICATIONS AND USAGE

Hydrocortisone acetate and pramoxine hydrochloride suppositories are indicated for use in inflamed hemorrhoids, post-irradiation (factitial) proctitis; as an adjunct in the treatment of chronic ulcerative colitis; cryptitis; and other inflammatory conditions of anorectum and pruritus ani.

CONTRAINDICATIONS

Hydrocortisone acetate and pramoxine hydrochloride suppositories are contraindicated in those patients having a history of hypersensitivity to hydrocortisone acetate or any of the components.

PRECAUTIONS

Do not use hydrocortisone acetate and pramoxine hydrochloride suppositories unless adequate proctologic examination is made.

If irritation develops, the product should be discontinued and appropriate therapy instituted.

In the presence of an infection, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, hydrocortisone acetate should be discontinued until the infection has been adequately controlled.

Carcinogenesis

No long term studies in animals have been performed to evaluate the carcinogenic potential of corticosteroid suppositories.

Pregnancy Category C

In laboratory animals, topical steroids have been associated with an increase in the incidence of fetal abnormalities when gestating females have been exposed to rather low dosage levels. There are no adequate and well controlled studies in pregnant women.

Hydrocortisone acetate and pramoxine hydrochloride suppositories should only be used during pregnancy if the potential benefit justifies the 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.

It is not known whether this drug is excreted in human milk and because many drugs are excreted in human milk and because of the potential for serious adverse reactions in

nursing infants from hydrocortisone acetate and pramoxine hydrochloride suppositories, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

ADVERSE REACTIONS

The following local adverse reactions have been reported with hydrocortisone acetate suppositories; burning, itching, irritation, dryness, folliculitis, hypopigmentation, allergic contact dermatitis, secondary infection.

To report an adverse event, please contact Pageview Pharmaceuticals, LLC at 1-636-399-9417.

DRUG ABUSE AND DEPENDENCE

Drug abuse and dependence have not been reported in patients treated with hydrocortisone acetate suppositories.

OVERDOSAGE

If signs and symptoms of systemic overdosage occur, discontinue use.

DOSAGE AND ADMINISTRATION

FOR RECTAL ADMINISTRATION. Detach one suppository from strip of suppositories.

Hold suppository upright and carefully separate tabs at top opening and pull downward from the pointed end to expose the suppository. Remove the suppository from the pocket. Avoid excessive handling of suppository which is designed to melt at body temperature. Insert one suppository rectally, pointed end first. Insert one suppository in the rectum twice daily, morning and night for two weeks, in nonspecific proctitis. In more severe cases, one suppository three times a day or two suppositories twice daily. In factitial proctitis, the recommended duration of therapy is six to eight weeks or less, according to the response of the individual case.

HOW SUPPLIED

Hydrocortisone acetate 25mg and Pramoxine Hydrochloride 18 mg Suppositories are off-white, smooth surfaced and bullet shaped with one pointed end.

Box of 12 suppositories, NDC 73028-401-12

STORAGE

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Excursions permitted to 15°-30°C (59°-86°F). Store away from heat. Protect from freezing. Avoid contact with eyes.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

PHARMACIST: This product is not an Orange Book rated product, therefore all

prescriptions using this product shall be subject to state and federal statutes as applicable. This product has not been subjected to FDA therapeutic or other equivalency testing. There are no claims of bioequivalence or therapeutic equivalence. Each person recommending a prescription substitution using this product shall make such recommendation based on his/her professional knowledge and opinion, upon evaluating the active ingredients, inactive ingredients, excipients and chemical information contained within the enclosed prescribing information.

Rx Only

Manufactured for:

Pageview Pharmaceuticals

Maryland Heights, MO 63146

Rev. 01/22

PRINCIPAL DISPLAY PANEL - 12 Suppository Blister Pack Box

NDC 73028-401-12

PAGEVIEW
PHARMACEUTICALS

Hydrocortisone Acetate 25 mg
Pramoxine Hydrochloride 18 mg
Suppositories

FOR RECTAL USE ONLY

MADE IN
USA

12 Suppositories
Unit Dose

Rx Only

HYDROCORTISONE ACETATE PRAMOXINE HYDROCHLORIDE

hydrocortisone acetate and pramoxine hydrochloride suppository

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73028-401
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone Acetate (UNII: 3X7931PO74) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone Acetate	25 mg

Pramoxine Hydrochloride (UNII: 88AYB867L5) (Pramoxine - UNII:068X84E056)	Pramoxine Hydrochloride	18 mg

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73028-401-12	2 in 1 BOX	01/24/2022	
1	NDC:73028-401-01	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/24/2022	

Labeler - Pageview Pharmaceuticals (117003305)

Revised: 2/2022 Pageview Pharmaceuticals