Lauromacrogol 400 + Hydrocortisone acetate

Korto-S
27mg / 5mg Rectal Suppository
Antihemorrhoidal

FORMULATION:
Each suppository contains

Lauromacrogol 400	27mg
Hydrocortisone acetate	5 mg

PHARMACOLOGIC PROPERTIES:

Pharmacodynamic properties:
Hydrocortisone acetate has antiphlogistic, antipruritic and vasoconstrictive effects. It prevents edema and itching in a short time.

Lauromacrogol is a local anesthetic agent that suppresses the pain sensation.

Pharmacologic properties:
Absorption:
Approximately 26 % of hydrocortisone acetate is absorbed when applied in the form of suppository. However if the application surface is injured or inflamed, absorption of hydrocortisone acetate may increase.

Distribution:
Approximately 90% of hydrocortisone acetate bounds to plasma proteins.

Biotransformation:
Hydrocortisone acetate is metabolized in the liver and converted to its metabolites, tetrahydro cortisone and tetrahydrocortisole.

Elimination:
Hydrocortisone acetate is metabolized to biologic inactive components including glucoronide and sulphate metabolites in tissues and liver. These inactive metabolites and a small amount of remained part is excreted in the urine.

INDICATIONS:
Internal and external hemorrhoids (simple and inflammatory), anal fissure, post irradiation proctitis, anal eczema and pruritus ani.

CONTRAINDICATION:
This product should not be used in those patients who have hypersensitivity to the ingredients of the product.

It should not be used in tuberculosis of rectum and anal region, fungal infections and during living virus vaccinations.

Due to the risk of systemic side effects, it should be used with caution in patients with peptic ulcer, osteoporosis, psychosis, severe psychoneurosis, diabetes, congestive heart failure, chronic renal failure and in elderly patients. However the amount of hydrocortisone acetate of the preparation and its rectal absorption rate are low.

WARNINGS / PRECAUTION:
Do not use unless proctologic examination is made. If irritation occurs, application should be discontinued. In the presence of an infection, appropriate antifungal or antibacterial agents should be administered. If a desirable response does not occur promptly, the usage of corticosteroid should be discontinued until the infection has been adequately controlled.

- During prolonged corticosteroid treatment, the patients should be followed regularly in terms of hypertension, glycosuria, hypokalemia, gastric disorders and mental changes.
- The suppositories should not be kept at too hot places and under sun. It is not necessary to store in refrigerator.
- Casing strip should be cut with scissor. If the casing strip has been torn by hand, the adjacent suppository gets dry and dissolution is impaired.

PREGNANCY AND LACTATION:
Pregnancy category is C.

Women of childbearing potential / Contraception

There are no suffient data to use this suppository in pregnant women. Studies conducted in animals have shown teratogenic effect of hydrocortisone. Hydrocortisone is thought to carry a small risk on the human fetus.

The benefit / risk ratio in the treatment with this product should be evaluated by a physician and should not be used in pregnancy unless it is necessary.

Pregnancy

Hydrocortisone and its inactive precursor cortisone are thought to carry a small risk on the human fetus during pregnancy.

Lactation Period

If the usage of the product is found necessary, nursing mothers should be treated by considering the importance of the drug for the patient. During this period, breast-feeding should be discontinued.

Reproduction / Fertility

There are no data regarding the effects on reproduction or fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:
No effects on ability to drive and use machines.

ADVERSE REACTIONS:

Local adverse reactions: Burning, itching, hypertrichosis, telangiectasia, mucosa atrophy, irritation, dryness, folliculitis, hypopigmentation, secondary infection, allergic contact dermatitis.

This product is applied to anorectal tissue for local effects. It has been reported that 26% of hydrocortisone acetate, which is administered by the rectal route in suppository form, is absorbed. However, absorption may vary from inflamed surfaces. During prolonged use of high dosages of this product, an amount which is high enough to cause systemic effects may be absorbed. Its use may delay healing of wounds.

The frequency of adverse events listed below is defined using the following convention:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1.000 to <1/100), rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (cannot be estimated from the available data)

Adverse effects seen depending on the systemic effects are listed below:

Adverse effects of hydrocortisone acetate

Metabolism and nutrition disorders:
Uncommon: Water and salt retention (edema)
Unknown: Decrease in glucose tolerance

Psychiatric disorders:
Unknown: Psychical disorders

Cardiac disorders:
Uncommon: Increase of arterial pressure in patients with hypertensions

Gastrointestinal disorders:
Uncommon: Peptic ulcer reactivation
Unknown: Increase in the secretion of gastric

Skin and subcutaneous tissue disorders:
Uncommon: Acne

Musculoskeletal and connective tissue disorders:
Unknown: Osteoporosis

Renal and urinary disorders:
Uncommon: Loss of potassium, Cushing sendrom (during prolonged use)
Unknown: Inhibition of adrenal cortex

INFORM YOUR PHYSICIAN WHENEVER AS UNEXPECTED EFFECT IS OBSERVED.

DRUG INTERACTION:
This product is applied for local effect. Drug interactions may be observed only after systemic application.

DOSAGE AND ADMINISTRATION:

Posology / Frequency and duration of administration:
Unless advised otherwise by a physician, 1 or 2 suppositories should be used daily. Duration of treatment is determined by a physician according to the individual's response to the medication.

Since long-term uses and high doses may cause systemic corticosteroid effects, it is not recommended to use for more than 7 days.

Method of administration:

This product is used only for rectal medication. Suppositories are inserted rectally after defecation and the anal area is covered with a small piece of cotton. Patient should remain in lying position for a while. In cases when feces must be softened, appropriate laxatives should be used and an appropriate diet should be recommended.

Additional information about special populations:

Renal / Liver failure: It should not be used in patients with renal / liver disorders.

Pediatric population: It should not be used in children.

Geriatric population: It should not be used in elderly.

OVERDOSAGE:
If overdosage occurs, consult a physician immediately.

STORAGE CONDITION:
Store at temperatures not exceeding 30^0C.

AVAILABILITY:
PVC/PE duplex foil casing strip x 5's; Box of 10's rectal suppositories

CAUTION: Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADVERSE DRUG REACTION
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

Registration No.: DR-XY44365

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Date of First Authorization: March 2015
Date of Product Insert Revision: September 2022