Cortenema® P_r

Hydrocortisone

Glucocorticoid

Aptalis Pharma Canada Inc.

Indications: An adjunct in the treatment of nonspecific inflammatory diseases involving the rectum, sigmoid and left colon such as idiopathic ulcerative colitis, ulcerative proctitis, regional enteritis (granulomatous colitis) with left side involvement, proctitis, proctocolitis, and radiation proctitis.

Contraindications: Local contraindications to the use of intrarectal steroids include obstruction, abscess, perforation, peritonitis, fresh intestinal anastomoses, extensive fistulas and sinus tracts.
Active tuberculosis (active, latent or nonpositively healed), ocular herpes simplex, and acute psychosis are usually considered absolute contraindications to the use of corticosteroids.
Relative contraindications include active peptic ulcer, acute glomerulonephritis, myasthenia gravis, osteoporosis, diverticulitis, thrombophlebitis, psychic disturbances, pregnancy, diabetes, hyperthyroidism, acute coronary disease, hypertension, limited cardiac reserve, and local or systemic infections, including fungal, viral or exanthematous diseases. Where these conditions exist, the expected benefits from hydrocortisone retention enema must be weighed against the risks involved in its use.
If there is no evidence of clinical or proctologic improvement within 2 or 3 weeks after starting hydrocortisone retention enema therapy, discontinue the drug.

Warnings: No data supplied by the manufacturer.

Precautions: Hydrocortisone retention enema should be administered with caution in patients with severe ulcerative disease because these patients are predisposed to perforation of the bowel wall. In the advanced stages of chronic ulcerative colitis, where there is loss of mucosa, and thickening and fibrosis of the bowel wall, steroid therapy theoretically might hasten deterioration, although this has not been proved with steroids in actual practice.
In severe cases, such as acute fulminating ulcerative colitis, where surgery is imminent, in the absence of marked clinical improvement, it is hazardous to wait more than a few days for a satisfactory response to medical treatment.
Of particular importance is the complication of adrenal insufficiency caused by suppression of the adrenal cortex by glucocorticoids, especially after prolonged therapy. It is therefore important that therapy be withdrawn gradually.
If the patient is subjected to unusual stress, while on therapy or up to a year after discontinuation of steroids, adequate supportive measures and increased or reinstated systemic steroid therapy are indicated.
In the case of surgery, these measures should be continued throughout the pre- and the postoperative recovery periods, bearing in mind the possible deleterious effects of corticosteroids on fresh intestinal anastomoses. Steroid therapy might impair the prognosis in surgery by increasing the hazard of infection. If infection is suspected, appropriate antibiotic therapy must be administered, usually in doses larger than those customarily employed.
General precautions common to all corticosteroids therapy should be observed during treatment with hydrocortisone retention enema, including those pertaining to growth suppression in children during prolonged use.
Patients should be kept under close observation, for, as with all drugs, rare individuals may react unfavorably under certain conditions.
If severe reactions or idiosyncrasies occur, steroids should be discontinued immediately and appropriate measures instituted.
Pregnancy: If it is necessary to use hydrocortisone retention enema in pregnant patients, the infants of these mothers should be closely observed following delivery for signs of hypoadrenalism and appropriate measures, including administration of corticosteroids, should be instituted if such signs are seen.
Corticosteroid therapy may cause hyperacidity or peptic ulcer, and may aggravate diabetes mellitus or precipitate manifestations of latent diabetes mellitus.
When hydrocortisone retention enema is used in the presence of glaucoma, intraocular pressure should be measured frequently and optic nerve heads and visual fields observed.
Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

Adverse Effects: Hydrocortisone retention enema may produce adverse effects known to occur with other forms of hydrocortisone therapy. These include moon face, buffalo hump, fluid retention, excessive appetite and weight gain, abnormal fat deposits, mental symptoms, hypertrichosis, acne, striae, ecchymosis, increased sweating, pigmentation, dry scaly skin, thinning scalp hair, thrombophlebitis, decreased resistance to infection, negative nitrogen balance with delayed bone and wound healing, menstrual disorders, neuropathy, peptic ulcer, decreased glucose tolerance, hypopotassemia, adrenal insufficiency, necrotizing angiitis, hypertension, pancreatitis and increased intraocular pressure.
In children, suppression of growth may occur. Increased intracranial pressure may occur and possibly account for headache, insomnia and fatigue. Subcapsular cataracts may result from prolonged usage. Long-term use of all corticosteroids results in catabolic effects characterized by negative protein and calcium balance. Osteoporosis, spontaneous fractures and aseptic necrosis of the hip and humerus may occur as part of this catabolic phenomenon.
Where hypokalemia and the other symptoms associated with fluid and electrolyte imbalance call for potassium supplementation and salt-poor or salt-free diets, these may be instituted and are compatible with the diet requirements for ulcerative colitis.

Overdose:

For management of a suspected drug overdose, CPhA recommends that you contact your **regional Poison Control Centre**. See the *CPS* Directory section for a list of Poison Control Centres.

Treatment: No known antidote but gastric lavage should be performed.

Dosage: The usual dose is one 60 mL enema (100 mg hydrocortisone) daily for 2 or 3 weeks, and every second day thereafter, administered intrarectally in the evening before retiring. Every effort should be made to retain the medication at least 1 hour, and preferably all night. This may be facilitated by prior sedation and/or antidiarrheal medication. Certain cases may require 2 doses a day (30 or 60 mL) until alleviation of symptoms allows better retention. If clinical or proctologic improvement fail to occur within 2 or 3 weeks, hydrocortisone retention enema therapy should be discontinued.

For administration by retention enema, instruct the patient to lie on his left side during instillation of the medication. Shake the bottle vigorously to resuspend the insoluble portion of hydrocortisone. Expose the lubricated tip by removal of the protective sheath, grasping the bottle at the neck where it is most rigid. Carefully, insert the lubricated tip into the rectum in the direction of the sacrum. Slowly express the contents by compressing the container. After instillation, the patient should remain in the same position (on left side) for at least 30 minutes, to allow distribution of the medication in the colon. The 60 mL hydrocortisone retention enema may be expected to distribute throughout the descending colon and rectum.

The duration of treatment is dependent on the degree of response. If a satisfactory response is to be obtained, it usually occurs within 5 to 7 days, as evidenced by a marked reduction of clinical symptoms. Improvement in the appearance of the mucosa, gauged by barium enemas and sigmoidoscopic examinations, may lag somewhat behind clinical improvement.

The usual duration of therapy is 2 weeks.

Minimal control of symptoms is an insufficient basis for the prolonged use of CORTENEMA. If there is no clinical or proctologic response within 2 or 3 weeks, or if the patient's condition worsens, discontinue the drug.

Because of hydrocortisone absorption, proper precautions against unwanted systemic reactions or side effects should be observed. Symptomatic improvement, evidenced by decreased diarrhea, weight gain, improved appetite, lessened fever, and decrease in leukocytosis, may be misleading and should not be used as the sole criterion in judging efficacy. Actual sigmoidoscopic examination and x-ray visualization are most reliable. Since steroids can inhibit wound healing, enema or drip therapy should not be employed in the immediate or early postoperative period following ileorectostomy.

Supplied: Each single-dose unit contains: hydrocortisone USP 100 mg in 60 mL of an aqueous suspension. Nonmedicinal ingredients: carboxypolymethylene, polysorbate 80, methylparaben, purified water and sodium hydroxide.
Lactose-, sulfite- and tartrazine-free. Boxes of 7.