CORTENEM®
hydrocortisone retention enema
100 mg / 60 mL
DISPOSABLE UNIT FOR Rectal USE ONLY

DESCRIPTION
Hydrocortisone is a white to practically white, odorless, crystalline powder very slightly soluble in water. It has the chemical name C21H28O2S. "Corticosteroids" and "steroid hormones" generally refer to the naturally occurring hormones that are used in corticosteroid treatment.

CLINICAL PHARMACOLOGY
Hydrocortisone produces a rapid suppression of inflammatory responses. Hydrocortisone reduces edema, pain, and swelling associated with the inflammation. It is used to treat conditions such as arthritis, skin disorders, and some internal diseases.

INDICATIONS AND USAGE
CORTENEM® is indicated for the treatment of inflammatory conditions such as dermatitis, contact dermatitis, and other skin disorders. It may also be used to reduce inflammation associated with some internal conditions such as rheumatoid arthritis.

CONTRAINDICATIONS
CORTENEM® is contraindicated in patients who are hypersensitive to corticosteroids or related substances.

WARNINGS
In patients who are on long-term therapy, there is a risk of developing Cushing's syndrome. This risk increases with the duration of therapy and the potency of the drug. The risk is less with the long-acting preparations. The most frequent signs and symptoms of Cushing's syndrome are: weight gain, acne, fluid retention, hypertension, edema, easy bruising, increased susceptibility to infections, osteoporosis, and psychiatric disturbances.

Usage in pregnancy:
CORTENEM® is not recommended for use during pregnancy or lactation.

Usage in children:
CORTENEM® is not recommended for use in children.

Dosage and Administration:
The recommended dosage for CORTENEM® is 100 mg rectally, twice daily. The dosage may be increased up to 150 mg twice daily if needed.

Pregnancy:
CORTENEM® is contraindicated in pregnant women.

Lactation:
CORTENEM® is contraindicated in breastfeeding women.

Elderly:
CORTENEM® is not recommended for use in elderly patients.

Drug Interactions:
CORTENEM® may enhance the effects of other drugs that increase blood pressure or heart rate, such as beta-blockers, calcium channel blockers, and sympathomimetics.

ADVERSE REACTIONS:
The most common adverse reactions associated with the use of CORTENEM® are: acne, skin atrophy, increased blood pressure, and fluid retention. Other less common reactions include: diabetes mellitus, hyperglycemia, and hyperlipidemia.

NURSING CONSIDERATIONS:
CORTENEM® is not recommended for use in nursing mothers.

Precautions:
CORTENEM® should be used cautiously in patients with a history of peptic ulcer disease or a history of gastrointestinal bleeding.

DRUG ABUSE AND DEPENDENCE:
CORTENEM® may be habit-forming if used for prolonged periods. It is not recommended for use in patients with a history of addiction.

OVERDOSAGE:
Overdosage of CORTENEM® may cause serious side effects such as hypertension and fluid retention. Treatment should consist of supportive care and management of symptoms.

STORAGE:
Store at room temperature.

PATIENT INFORMATION:
CORTENEM® is a prescription medication. It is not recommended for use by children or pregnant or breastfeeding women. It is not recommended for use by patients with a history of peptic ulcer disease or a history of gastrointestinal bleeding.

CORTENEM® should be used cautiously in patients with a history of peptic ulcer disease or a history of gastrointestinal bleeding.

DRUG ABUSE AND DEPENDENCE:
CORTENEM® may be habit-forming if used for prolonged periods. It is not recommended for use in patients with a history of addiction. The usual course of therapy is one CORTENEM® nightly for 21 days, or until the patient has achieved remission and can be maintained on a maintenance dosage.
PATIENT INSTRUCTIONS

How to use the retention enema:
Best results are achieved if the bowel is emptied immediately before the enema is given.

1 Preparing the Medication for Administration
   a Shake the bottle well to make sure that the suspension is homogeneous.
   b Remove the protective sheath from the applicator tip. Hold the bottle at the neck so as not to cause any of the medication to be discharged.

2 Assuming the Correct Body Position
   a Best results are obtained by lying on the left side with the left leg extended and the right leg flexed forward for balance.
   b An alternative to lying on the left side is the "knee-chest" position as shown here.

3 Administering the Retention Enema
   a Gently insert the lubricated applicator tip into the rectum, pointed slightly toward the navel (umbilicus).
   b Grasp the bottle firmly, then tilt slightly so that the nozzle is aimed toward the back, and squeeze slowly to instill the medication. Steady hand pressure will discharge most of the solution. After administering, withdraw and discard the used unit.
   c Remain in position for at least 30 minutes to allow thorough distribution of the medication internally. Retain the enema all night, if possible.