Purified Cortrophin™ Gel (repository corticotropin) – New drug approval

- November 1, 2021, ANI Pharmaceuticals announced the FDA approval of Purified Cortrophin Gel (repository corticotropin), for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis (MS) and rheumatoid arthritis, in addition to excess urinary protein due to nephrotic syndrome.
    - For a complete list of indications, refer to the Purified Cortrophin Gel drug label.
- Cortrophin Gel is an adrenocorticotropic hormone (ACTH), also known as purified corticotropin.
    - The only other FDA approved corticotropin-based therapy is Acthar® Gel.
- Purified Cortrophin Gel is contraindicated:
    - For intravenous administration
    - In patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, or sensitivity to proteins derived from porcine sources
    - In patients with primary adrenocortical insufficiency or adrenocortical hyperfunction.
- Warnings and precautions for Purified Cortrophin Gel include masking symptoms of other diseases; immunogenicity potential; ophthalmic effects; infections; elevated blood pressure, salt and water retention, and hypokalemia; vaccination; adrenal insufficiency; use in patients with hypothyroidism and cirrhosis; use in patients with latent tuberculosis or tuberculin reactivity; comorbid diseases; growth and development; acute gouty arthritis; drug interactions; and pregnancy.
- The most common adverse reactions with Purified Cortrophin Gel are fluid or sodium retention; muscle weakness; osteoporosis; peptic ulcer with possible perforation and hemorrhage; impaired wound healing; hypertension; convulsions; headache; development of Cushingoid state; and suppression of growth in children.
    - These are not all the adverse reactions reported with Cortrophin Gel. Refer to the drug label for a complete listing.
- Verification tests should be performed prior to treatment with corticotropins. Standard tests for verification of adrenal responsiveness to corticotropin may utilize as much as 80 units as a single injection or one or more injections of a lesser dosage. Following verification dosage should be individualized according to the disease under treatment and the general medical condition of each patient. Frequency and dose of the drug should be determined by considering severity of the disease, plasma and urine corticosteroid levels and the initial response of the patient. Only gradual change in dosage schedules should be attempted, after full drug effects have become apparent.
    - Purified Cortrophin Gel should be administered subcutaneously or intramuscularly.
    - In the treatment of acute exacerbations of MS, the recommended dosage is daily intramuscular doses of 80 to 120 units for 2 to 3 weeks.
    - The chronic administration of more than 40 units daily may be associated with uncontrollable adverse effects.

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- ANI Pharmaceuticals plans to launch Purified Cortrophin Gel in early first quarter 2022. Purified Cortrophin Gel will be available in 5 mL multiple-dose vials containing 80 USP units/mL.