H.P. Acthar Gel Dosage

Generic name: CORTICOTROPIN 80[USP'U] in 1mL
Dosage form: injection
Drug class: Corticotropin

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Important Information

Acthar Gel vial is intended for either intramuscular or subcutaneous injection.

Acthar Gel single-dose pre-filled SelfJect injector is for subcutaneous administration by adults (18 years of age and older) only. The single-dose pre-filled SelfJect injector should only be used to administer single doses of either 40 units or 80 units. For administration of doses other than 40 units or 80 units, use the Acthar Gel multi-dose vial.

Recommended Dosage for Infantile Spasms in Infants and Children Under 2 Years of Age

In the treatment of infantile spasms, Acthar Gel must be administered intramuscularly using the Acthar gel vial. Do not use the Acthar Gel single-dose pre-filled SelfJect injector for the treatment of infantile spasms. The recommended regimen is a daily dose of 150 U/m^2 (divided into twice daily intramuscular (IM) injections of 75 U/m^2) administered over a 2-week period. Dosing with Acthar Gel should then be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m^2 in the morning for 3 days; 15 U/m^2 in the morning for 3 days; 10 U/m^2 in the morning for 3 days; and 10 U/m^2 every other morning for 6 days.

Acthar Gel is typically dosed based on body surface area (BSA). For calculation of body surface area, use the following formula:

$$BSA(m^2) = \sqrt{\frac{weight\ (kg) \times height\ (cm)}{3600}}$$

Recommended Dosage for the Treatment of Acute Exacerbations in Adults with Multiple Sclerosis

The recommended dose is daily intramuscular or subcutaneous doses of 80 to 120 units for 2-3 weeks for acute exacerbations.

Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Although drug dependence does not occur, sudden withdrawal of Acthar Gel after prolonged use may lead to adrenal

insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Recommended Dosage for Other Indications for Adults and Children Over 2 Years of Age

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 and the initial response of the patient.

The usual dose of Acthar Gel is 40 to 80 units given intramuscularly or subcutaneously every 24 to 72 hours.

Although drug dependence does not occur, sudden withdrawal of Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

Preparation and Administration

Visually inspect the liquid for particulate matter and discoloration prior to administration. Acthar Gel must not be injected if the solution is cloudy or contains particulate matter.

Acthar Gel Multi-Dose Vial

- Warm to room temperature before using.

- Take caution to not over-pressurize the vial prior to withdrawing the product.

Acthar Gel Single-Dose Pre-filled SelfJect Injector

Preparation

- Prior to injection, remove from the refrigerator and sealed tray and allow to sit for 45 minutes to warm to room temperature.

Administration

- Read the FDA-approved Instructions for Use carefully before administering.

- Administer by subcutaneous injection only. Acthar Gel single-dose pre-filled SelfJect injector is not for intramuscular injection.

- Inject in the upper thigh, abdomen, or back of arm. Avoid injecting within 1 inch of navel, knee, or groin area.

- Avoid areas with scars, tattoos, warts, birthmarks, or stretch marks, or where the skin is irritated.

- Rotate injection sites. Do not use the same site more than one time per week.

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CSA Schedule*
N/A Not a controlled drug

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