Synacthen® (tetracosactide acetate) Ampoules 250 micrograms Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing
Presentation: Each Synacthen ampoule contains 250 micrograms of tetracosactide acetate.
Indication: Diagnostic test for the investigation of adrenocortical insufficiency.
Dosage and administration: For diagnostic purposes only as a single intramuscular or intravenous dose. Not to be used for repeated therapeutic administration.
Adults and Elderly: For the 30-minute Synacthen diagnostic test: 250 micrograms (1 ml) of Synacthen is given via intramuscular or intravenous injection and blood sampling is performed immediately before and exactly 30 minutes after. Please see Synacthen SmPC for full directions on carrying out diagnostic test.
Children: Suggested intravenous dose of 250 micrograms/1.73 m^2 body surface area.
Contraindications: Hypersensitivity to tetracosactide and/or ACTH or to any of the excipients. In patients with allergic disorders (e.g. asthma), acute psychosis, infectious diseases, peptic ulcer, refractory heart failure, Cushing's syndrome, treatment of primary adrenocortical insufficiency and adrenocongenital syndrome.
Special warnings and precautions: Exclude allergic conditions or history of adverse reactions to ACTH, Synacthen or other drugs. Administer under the supervision of appropriate senior hospital medical staff. Observe for 30 minutes after injection for signs of hypersensitivity. If local or systemic reactions occur, discontinue Synacthen or other ACTH preparation, treat patient appropriately and avoid product in the future. Not to be used in presence of active infection or systemic diseases, with live vaccine or in reduced immune response unless adequate disease specific therapy is being given. Use with caution in patients with ulcerative colitis, diverticulitis, recent intestinal anastomosis, kidney failure, hypertension, predisposition to thromboembolism, osteoporosis, myasthenia gravis and ocular herpes simplex. Increased production of adrenal steroids may result in corticosteroid type effects; psychological disturbances may be triggered, existing emotional instability or psychotic tendencies may be aggravated; latent infections may become activated; ocular effects may be produced and there may be a need for dose adjustment in patients with diabetes or hypertension. Contains less than 1 mmol sodium (23 mg) per ampoule.
Lack of diagnostic accuracy: Patients on oral contraceptives, post-operative patients, critical illness, severe liver disease, nephrotic syndrome may cause misleading post administration total plasma cortisol levels during Synacthen test. Assess the integrity of HPA axis using alternate parameters.
For further information on special warnings, precautions and interactions please refer to SmPC.
Pregnancy and lactation: Synacthen should be used during pregnancy only if expected benefit outweighs potential risk to foetus and should be used with caution in women who are breastfeeding.
Undesirable effects: *Relating to tetracosactide*: Adrenal haemorrhage and hypersensitivity reactions. Hypersensitivity reactions may include skin reactions at the injection site, dizziness, nausea, vomiting, urticaria, pruritus, flushing, malaise, dyspnoea, angioneurotic oedema and Quincke's oedema. Tend to be more severe (anaphylactic shock) in those susceptible to allergies. Other side effects relating to glucocorticoid and mineralocorticoid effects are unlikely to be observed with the use of Synacthen as a diagnostic tool. **Please refer to SmPC for full details**.
Legal category: POM
Presentation and cost: one ampoule (1 ml) £38.
Marketing authorisation holder and number: Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon SS14 3FR, UK. PL43252/0026.
Date of last revision: February 2020.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Atnahs Pharma UK Limited on +44 (0) 1279 406759 or by email to atnahspv@diamondpharmaservices.com