PACKAGE LEAFLET: INFORMATION FOR THE USER

Synacthen 250 micrograms/ml, solution for injection
(Tetracosactide)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

1. WHAT SYNACTHEN 250 MICROGRAMS/ML IS AND WHAT IT IS USED FOR

Synacthen ampoules contains tetracosactide. This is a substance which stimulates the adrenal glands to produce certain hormones.

Synacthen (tetracosactide) is used as a test to find out the cause of certain hormonal problems e.g., low levels of the hormone cortisol as in Addison's disease. Two blood samples will be taken, one before the injection of Synacthen and the other 30 minutes after injection. These blood samples will show whether your adrenal glands are functioning as well as they should by measuring the hormone levels.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE SYNACTHEN 250 MICROGRAMS/ML

Do not take Synacthen:

- if you are allergic (hypersensitive) to tetracosactide and/or ACTH (Adrenocorticotropic hormone) or any of the other ingredients of this medicine (listed in section 6).
- If you have allergic disorders (e.g. asthma).

Warnings and precautions
Talk to your doctor or nurse before using Synacthen if you have previously experienced adverse reactions to ACTH, Synacthen or other drugs.

Take special care with Synacthen 250 micrograms/ml

- Synacthen may interact with routine drug testing in athletes.

Other medicines and Synacthen

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Synacthen brings about an increase in adrenocortical production of glucocorticoids (a steroid hormone) and mineralocorticoids, drug interactions of the type seen with these corticosteroids (steroid hormone) may occur.
- Patients receiving medication for diabetes mellitus or for moderate to severe hypertension (high blood pressure) must have their dosage adjusted if treatment with Synacthen is started.

Synacthen 250 micrograms/ml with food and drink

No information available.

Pregnancy and breast-feeding

Pregnancy
If you are pregnant or think you may be pregnant, tell your doctor. Your doctor will discuss with you the potential risk of using Synacthen during pregnancy.
Lactation
If you are breast-feeding, tell your doctor. Synacthen should be given with caution to women who are breast-feeding.
Fertility
There is no data available.

Driving and using machines

Since Synacthen may have an effect on the central nervous system, patients should be very cautious when driving vehicles or using machines.

Synacthen 250 micrograms/ml contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially "sodium- free".

3 HOW TO USE SYNACTHEN 250 MICROGRAMS/ML

The liquid in the ampoule will be drawn up into a syringe and injected into a muscle or in a vein by your doctor or nurse.

Adults

This preparation of Synacthen is intended for administration for diagnostic purposes only. It may be administered as a single dose into a vein or muscle.
The 30-minute Synacthen diagnostic test is based on measurement of the concentration of cortisol in the plasma (the liquid in your blood excluding the blood cells) immediately before and exactly 30 minutes after a dose of 1 ml (250 micrograms) Synacthen has been administered into a vein or muscle. Adrenocortical function can be regarded as normal if the concentration of cortisol in the plasma after dose injection (administration with Synacthen) amounts to at least 200 nmol/litre (70 micrograms/litre).

Use in the elderly (age 65 years and over)

There is no evidence to suggest that dosage should be different in the elderly over the age of 65.

Use in children and adolescents

The dosage will be administered into a vein. The concentration is decided by the physician and will be around 1 ml (250 micrograms) per 1.73 m^2 body surface area. For children aged 5-7 years, approximately half the adult dose will be adequate.

If too much Synacthen 250 micrograms/ml is given

Synacthen is given to you by a doctor or a nurse and it is very unlikely that an overdose will happen. Overdosage is unlikely to be a problem when the product is used as a single dose for diagnostic purposes.

4 POSSIBLE SIDE EFFECTS

Like all medicines, Synacthen can cause side effects, although not everybody gets them.

Undesirable effects related to Synacthen

- **Some effects could be serious:**If you have *hypersensitivity reactions:* Synacthen can provoke hypersensitivity reactions, which tend to be more severe (anaphylactic shock) in patients susceptible to allergies (especially asthma).
  Hypersensitivity reactions may include skin reactions at the injection site, dizziness, nausea, vomiting, hives, itching, flushing, general feeling of being unwell, shortness of breath and/or a rapid swelling of the skin and mucous membranes (angioneurotic oedema or Quincke's oedema).
- If you have bleeding of the adrenal gland, a small gland above the kidneys. Symptoms of bleeding of the adrenal gland are sudden acute abdominal and flank pain.

If you experience any of these reactions you should tell a doctor **immediately**.

Infections and infestations	Increased susceptibility to infection, abscess
Blood and the lymphatic system disorders	An increase in white blood cells (leukocytosis)
Endocrine disorders	Irregular menstruation, Cushing's syndrome (a hormone disorder caused by high levels of cortisol in the blood) and a state when the pituitary does not produces enough hormone which may lead to a secondary adrenocortical insufficiency (when the adrenal glands are not working properly). Particularly in times of stress, e.g. after trauma, surgery or illness there may be a decreased carbohydrate tolerance, high blood sugars, manifestations of latent (dormant) diabetes mellitus and excessive hair growth.
Metabolism and nutrition disorders	Increased appetite, low blood potassium, calcium deficiency, retention of sodium and fluid in the body
Psychiatric disorders	Mental disorder
Nervous system disorders	Headache, vertigo, convulsions Optic disc swelling as a result of an increased preassure within the skull, usually after treatment
Eye disorders	Cataracts, increased pressure within the eyeball, glaucoma, bulging of the eye ball (exophthalmose)
Cardiac disorders	Congestive heart failure (heart failure in which the heart is

	unable to adequately pump out the blood), increased blood pressure Thickening of the heart muscle may occur in single cases in infants and small children treated over a prolonged period with high doses. This symptom will return to normal after end of treatment.
Vascular disorders	Blood clot (thromboembolism), inflammation of the blood vessel walls (necrotising vasculitis)
Gastrointestinal disorders	Peptic ulcer with possible perforation and bleeding, inflammation of the pancrease, abdominal distension, inflammation of the lining of the gullet
Skin and subcutaneous tissue disorders	Skin atrophy (cells of the skin wither away), red spots under the skin and brusing , erythema, increased perspiration, acne and skin hyper pigmentation
Musculoskeletal, connective tissue and bone disorders	Osteoporosis, muscular weakness, loss of muscle mass, compression fractures of the bones in the spine, bone death in the femoral and humeral heads (specific bones in the body), pathological fracture of long bones, tendon rupture
General disorders and administration site conditions	Hypersensitivity reactions, increased weight, impaired healing, retarded growth
Investigations	Negative nitrogen balance due to protein degradation, suppression of skin test reactions

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine

5 HOW TO STORE SYNACTHEN 250 MICROGRAMS/ML

Your medicine should be stored in the refrigerator (2–8°C). Keep ampoules in the outer carton to protect from light. Any solution remaining after injection should be discarded.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the label and box.
The product should be used immediately after opening.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Synacthen 250 micrograms/ml contains

- The active substance is 250 micrograms of tetracosactide. Each ampoule contains tetracosactide 250 micrograms, as tetracosactide acetate.

- The ampoules also contain glacial acetic acid, sodium acetate, sodium chloride and water for injections.

What Synacthen 250 micrograms/ml looks like and contents of the pack

The product is a clear, colourless aqueous solution in a type 1 (Ph. Eur.) clear glass 1 ml ampoule. The product is presented as a pack of 5 ampoules of 1 ml.

Marketing Authorisation Holder and Manufacturer

Manufactured by:
Alfasigma S.p.A.
Via Pontina Km 30.400
00071- Pomezia (Rome)
Italy

Doppel Farmaceutici srl
Via Volturno, 48
20089 Rozzano (Milan)
Italy

Product licence/authorisation holder:
Alfasigma S.p.A. –
Via Ragazzi del '99, n.5,
40133 Bologna (BO)
Italy

Local representative:
CD Pharma S.r.l.
Viale Cassiodoro, 16
20145 Milan
Italy
Tel. +39 02-43980539
info@cdpharmagroup.one

This leaflet was last revised