

SYNACTHEN i.m./i.v.[®]

(tetracosactide hexaacetate)

250 micrograms/mL Solution for injection or infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Synacthen.

Read all of this leaflet carefully before you are given SYNACTHEN i.m./i.v.[®]

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child having Synacthen against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

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

Keep this leaflet. You may need to read it again.

What Synacthen is and what it is used for

What Synacthen is

Synacthen belongs to a group of medicines called pituitary hormones and analogues.

Synacthen is supplied as a liquid solution in a 1 mL colourless glass ampoule.

Synacthen is given as an injection into a muscle or vein.

What Synacthen is used for

Synacthen is used as a diagnostic test to find out if the adrenal glands, small glands next to the kidneys, are working as well as they should.

Synacthen may also be used instead of steroids (medicines such as cortisone) to treat a number of different conditions:

- acute exacerbations of multiple sclerosis.
- some types of seizures in children.
- rheumatic diseases as a short-term therapy in conditions for which corticoids are normally used.
- skin diseases responsive to corticoids.
- ulcerative colitis and Crohn's disease.
- additional therapy in cancer patients to improve the tolerability of chemotherapy.

How Synacthen works

Synacthen works by stimulating the adrenal glands to increase the production of natural "steroid" hormones.

If you have any question about how Synacthen works or why this medicine has been prescribed for you, ask your doctor.

Before you are given Synacthen

This product should be given under medical supervision.

You should not be given Synacthen:

- If you are allergic (hypersensitive) to:
- tetracosactide or any of the other ingredients of Synacthen listed at the end of this leaflet, particularly benzylalcohol.
- a similar medicine called “ACTH” or “corticotrophin”.
- If you have asthma or other allergic conditions.
- If you have a serious mental illness with disturbances in thinking, feeling and behaviour.
- If you have any infectious disease.
- If you have a duodenal or stomach ulcer.
- If you have a severe heart disease.
- If you have Cushing’s syndrome, a condition of the adrenal glands causing weight gain, rounded face and high blood pressure.
- If you have an adrenocortical insufficiency (adrenal glands not working properly).
- If you have adrenogenital syndrome (adrenal glands not working properly).

If any of these conditions apply to you, tell your doctor as you should not be given Synacthen.

Take special care with Synacthen:

- If you have an underactive thyroid gland.
- If you have a severe liver disease (cirrhosis).
- If you have kidney problems.
- If you have been recently vaccinated.
- If you suffer from high blood pressure.
- If you have an inflammation of the bowel (e.g. ulcerative colitis or diverticulitis).
- If you have a predisposition to blockage of a blood vessel by a clot (thromboembolism).
- If you have osteoporosis (thinning of the bones).
- If you have myasthenia gravis (extreme muscle weakness).

If any of these apply to you, tell your doctor before you are given Synacthen.

If you suffer an injury or have surgery during Synacthen treatment or within one year after the end of the treatment, the Synacthen dose may have to be increased or Synacthen treatment restarted.

Since Synacthen can cause salt and water retention, your doctor may advise a low-salt diet during treatment. Whilst you are being treated with Synacthen, your doctor will regularly monitor your progress. Children receiving this medicine will be especially closely monitored.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These include medicines used to treat:

- diabetes.
- high blood pressure.
- convulsions

It may be necessary to change the dose or in some cases to stop the medicine.

Synacthen and older people

Synacthen can be used by people over the age of 65 at the same dose as other adults.

Synacthen and children

Children will be given a lower dose of Synacthen based on their age.

Pregnant women

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.

Breast-feeding mothers

If you are breast-feeding, tell your doctor. Synacthen should be given with caution to women who are breast-feeding.

Driving and using machines

Synacthen is not likely to affect your ability to drive or use machines.

How to use Synacthen

How much Synacthen should be given and when?

For the diagnosis of a hormonal problem only one dose of Synacthen is needed. For therapeutic use, your doctor will decide on a suitable dose of Synacthen depending on your condition.

Adults, including elderly patients will be given 250 micrograms (one ampoule).

How should Synacthen be given?

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.

For how long should Synacthen be given?

For diagnostic test use: You will be given a single injection of Synacthen. You will have two blood samples 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.

For therapeutic use: Synacthen will not cure your condition but it may relieve some of the symptoms. The injections can be continued for as long as they are beneficial.

If a Synacthen dose is missed

As a doctor or nurse is giving you this medicine, you are unlikely to miss a dose. If you have any worries, tell your doctor or nurse.

If too much Synacthen is given

Synacthen is given to you by a doctor or a nurse and it is very unlikely that an overdose will happen. If anyone accidentally receives this medicine, the nearest hospital emergency department or a doctor should be immediately contacted as medical attention may be required.

Stopping treatment with Synacthen

In the case of therapeutic use, treatment should be stopped gradually to help maintain the normal function of adrenal glands.

Possible side effects

Like all medicines, Synacthen can have side effects in some people.

Some effects could be serious:

- **If you have** an allergic reaction.
Symptoms of an allergic reaction may include redness or pain at the injection site, rash, itching, hives or flushing, dizziness, nausea or vomiting, difficulty breathing, swelling of the face, lips, tongue or other parts of the body.
- **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 at any time, **tell your doctor straight away or go immediately to the nearest hospital emergency department.**

When Synacthen Depot treatment is prolonged, other side effects may occur:

- **Endocrine disorders:** menstrual (period) problems, Cushing's syndrome (a condition of the adrenal glands causing weight gain, rounded face and high blood pressure), dysfunction of the adrenal glands (adrenocortical problem), increased blood sugar levels, increased body and facial hair.
- **Fluid and metabolic disturbances:** low calcium level in the blood (hypocalcaemia), low potassium level in the blood (hypokalaemia), high sodium level in the blood (hypernatraemia), swelling of hands, ankles or feet (fluid build-up in the body).
- **Neurological disorders:** mood changes, fits, headache, dizziness.
- **Ophthalmic disorders:** decreased or blurred vision, glaucoma (a condition in which the pressure of fluid in the eye is high), exophthalmos (protruding eyeballs).
- **Cardiac and vascular disorders:** high blood pressure, heart disease involving shortness of breath, swelling of the feet or legs due to fluid build-up in the body (oedema due to heart failure), reversible enlargement of the heart muscle, blockage of a blood vessel by a clot (thromboembolism), necrotising vasculitis.
- **Gastrointestinal disorders:** ulcer in stomach or duodenum, inflammation of the pancreas (pancreatitis), inflammation of the oesophagus (food pipe), stomach or abdominal pain or discomfort.
- **Skin disorders:** allergic reaction (see above also section "Some effects could be serious"), thinning of the skin, red or purple flat, pinhead spots under the skin, bruising, redness of the skin, acne.
- **Muscle and bone disorders:** muscle cramps or pain, muscle weakness, thinning of the bones (osteoporosis), destruction of bone tissue (aseptic necrosis of femoral and humeral heads), tendon rupture.
- **Others:** breathlessness, increased susceptibility to infection, excessive sweating, weight gain, growth retardation in children, increased white blood cells.

If any of these side effects persist or are troublesome, **tell your doctor.**

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Storing Synacthen

If you are storing Synacthen at home, keep it in the refrigerator.

Do not use after the expiry date shown on the box.

Store in the original package.

Keep out of the reach and sight of children.

Further information

What Synacthen is

- The **active substance** of Synacthen is tetracosactide hexacetate.
- The **other ingredients** are:
Acetic acid, sodium acetate, sodium chloride, water for injections.

What Synacthen looks like and contents of the pack

It is supplied as liquid solution in a 1 mL ampoule. Each ampoule contains 250 micrograms of tetracosactide.

Information for the health care professional

How to store Synacthen

Synacthen should be stored in a refrigerator (2-8°C), in the original package.

How to prepare and administer Synacthen

Synacthen must be injected intramuscularly (i.m.) or intravenously (i.v.) by a doctor or a nurse.

Sponsor

Synacthen is supplied in New Zealand by:

Novartis New Zealand Limited

Private Bag 65904

Mairangi Bay

Auckland

Building G, 5 Orbit Drive

Rosedale

Auckland 0632

Telephone 0800 652 422

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