

SYNACTHEN DEPOT i.m.[®]

(tetracosactide hexaacetate)

1 mg/mL Suspension for injection

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you are given SYNACTHEN DEPOT i.m.[®]
This leaflet answers some common questions about Synacthen Depot.

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 Depot 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 Depot is and what it is used for

What Synacthen Depot is

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

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

Synacthen Depot is given as an injection into a muscle.

What Synacthen Depot is used for

Synacthen Depot is 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.

Synacthen Depot may also be 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.

How Synacthen Depot works

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

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

Before you are given Synacthen Depot

This product should be given under medical supervision.

You should not be given Synacthen Depot:

- **If you are** allergic (hypersensitive) to:
 - tetracosactide or any of the other ingredients of Synacthen Depot 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).
- Synacthen Depot must not be used in premature babies and neonates. This is due to the presence of benzylalcohol, an ingredient that may cause toxic reactions and allergic reactions.

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

Take special care with Synacthen Depot:

- **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 Depot.

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

Since Synacthen Depot can cause salt and water retention, your doctor may advise a low-salt diet during treatment.

Whilst you are being treated with Synacthen Depot, 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 Depot and older people

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

Synacthen Depot and children

Children will be given a lower dose of Synacthen Depot 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 Depot during pregnancy.

Breast-feeding mothers

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

Driving and using machines

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

Information about some of the ingredients of Synacthen Depot

Synacthen Depot contains benzyl alcohol, which can cause toxic reactions and allergic reactions in children less than 3 years old.

How to use Synacthen Depot

How much Synacthen Depot should be given and when?

Your doctor will decide on a suitable dose of Synacthen Depot depending on your condition. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Adults

The starting dose is usually a single daily injection of 1 mg. In severe cases, it may be given twice a day. Once the condition has improved, the number of injections can usually be reduced to one every 2 or 3 days or even once weekly.

Children

The starting dose depends on the age of the child. The usual starting dose is a single daily injection ranging from 0.25 to 1 mg. Once the condition has improved, the number of injections can usually be reduced to one every 2 to 8 days.

How should Synacthen Depot be given?

The ampoules should be shaken before use. The liquid in the ampoule will be drawn up into a syringe and injected into a muscle by your doctor or nurse (never into a vein).

For how long should Synacthen Depot be given?

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.

For diagnostic test use: You will be given a single injection of Synacthen Depot. You will have six blood samples taken, one before the injection and the others 30 minutes, 1, 2, 3, 4 and 5 hours after injection. These blood samples will show whether your adrenal glands are functioning as well as they should.

If a Synacthen Depot 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 Depot is given

Synacthen Depot 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 contacted immediately as medical attention may be required.

Stopping treatment with Synacthen Depot

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 Depot 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, Cushings' 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), exophthalmus (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 Depot

If you are storing Synacthen Depot 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 Depot is

- The **active substance** of Synacthen Depot is tetracosactide hexaacetate.
- The **other ingredients** are:
Zinc chloride anhydrous pure, disodium hydrogen phosphate dihydrate, sodium chloride, benzylalcohol (10mg), water for injections.

What Synacthen Depot looks like and contents of the pack

Synacthen Depot is supplied as a liquid suspension in a 1 mL ampoule. One ampoule contains 1 mg of tetracosactide.

Information for the health care professional

How to store Synacthen Depot

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

How to prepare and administer Synacthen Depot

Synacthen Depot should be shaken before use.

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

Synacthen Depot must not be injected intravenously (i.v.).

Sponsor

Synacthen is supplied in New Zealand by:

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