PACKAGE LEAFLET : Information for the patient

Synacthen® Depot Ampoules 1mg/ml
Tetracosactide (as acetate)

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Synacthen Depot is and what it is used for

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

The pituitary gland is a small gland inside the brain which controls many other glands in the body, including the thyroid and adrenal glands. The pituitary gland produces hormones which send chemical messages to various parts of the body and affect many bodily functions such as blood pressure, blood sugar levels, growth and menstrual cycle.

The adrenal glands are found on top of the kidneys and make the body's natural steroids which can affect blood pressure and the way the body handles the sugars, protein and fats absorbed from food. They also make adrenaline which controls the body's response to different types of stress.

Synacthen Depot is similar to the hormone that the pituitary gland normally produces (called ACTH) to make the adrenal glands produce certain steroids. When Synacthen Depot is injected it works on the adrenal glands by 'telling' them to produce more steroids.

Synacthen Depot is used in place of medicines like prednisolone or cortisone (types of steroids) to treat a number of different conditions, including ulcerative colitis, Crohn's disease, rheumatoid arthritis and osteoarthrosis. It is usually only given for a short time.

Synacthen Depot is also used as a test to find out if the pituitary and adrenal glands are working normally.

2. What you need to know before you are given Synacthen Depot

You should not be given Synacthen Depot if:

- you are allergic (hypersensitive) to adrenocorticotropic hormone (ACTH), tetracosactide acetate or any of the other ingredients of Synacthen Depot (listed in Section 6)
- you suffer from any allergies, including allergies to any medicines
- you suffer from asthma
- you suffer from any serious mood or mental health disorders
- you have or have ever had tuberculosis
- you have currently got any infections
- you suffer from any known hormone problems, e.g. Cushing’s syndrome or Addison’s disease (over or under active adrenal glands)
- you have an ulcer in your stomach or small intestine
- you suffer from any serious heart disease
- it is for the treatment of primary adrenocortical insufficiency or adrenocongenital syndrome (where your adrenal glands are not working).

Warnings and precautions

Before you are given Synacthen Depot, tell your doctor or nurse if:

- you have been vaccinated recently or are planning to have a vaccination
- your immune system is not working properly
- you have any disorder of the intestines, e.g. ulcerative colitis, diverticulitis
- you have recently had surgery on your intestines (bowel)
- you suffer from high blood pressure
- you have suffered from a blood clot in the past
- you suffer from osteoporosis (thinning of the bones)
- you suffer from myasthenia gravis (an illness causing muscle weakness)
- you have an under active thyroid gland which can cause tiredness or weight gain
- you suffer from any serious liver or kidney disease
- you are pregnant, think you might be pregnant or are breast-feeding
- you have ocular herpes simplex (viral infection of the eye).

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.

Other medicines and Synacthen Depot
Tell your doctor or nurse if you are taking/using, have recently taken/used or might take/use any of the following medicines as they may interfere with Synacthen Depot:

- medicines to control high blood pressure
- medicines to control diabetes
- medicines to control convulsions (fits) such as valproate, phenytoin, clonazepam, nitrazepam, phenobarbital or primidone
- medicines to control conception (birth control).

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

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

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

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine. Your doctor will discuss with you the potential risk of using Synacthen Depot during pregnancy. Synacthen Depot should be given with caution to women who are breast-feeding.

Driving and using machines
If you feel dizzy or get blurred vision after you have been given Synacthen Depot, do not drive or operate machinery until these effects have worn off.

Synacthen Depot is essentially 'sodium-free' - it contains less than 1 mmol sodium (23 mg) per 1mg.

3. How to use Synacthen Depot

Your treatment with Synacthen Depot will take place in a hospital, under the supervision of a doctor. The doctor will be monitoring your progress carefully during your treatment with Synacthen Depot. Your doctor will decide on a suitable dose of Synacthen Depot depending on your condition.

Adults

Adults including elderly patients will usually start treatment with 1mg once or twice daily for about three days. As your condition improves, this dose will then be reduced over a period of several weeks, to 0.5mg every two to three days or 1mg once a week

Children

Children aged 3 -12 years will be given a lower dose based on their age and weight. They will start with an injection every day. This will then be reduced to once every 2 to 8 days.

Your doctor may monitor growth or organise heart scans in children who are given this medicine for a long period of time.

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 tests 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 the injection. These blood samples will show whether your adrenal glands are functioning as well as they should.

What to do if you think you have received more Synacthen Depot than you should

As this medicine is given to you in hospital, it is very unlikely that an overdose will happen. If anyone receives this medicine by accident, tell the hospital accident and emergency department or a doctor immediately. Show any left over medicines or the empty packet to the doctor.

If you forget to take Synacthen Depot

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

4. Possible side effects

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

Serious side effects:

- Anaphylactic shock or severe allergic reaction (symptoms may include redness or pain at the injection site, rash, itching, hives or flushing, dizziness, feeling or being sick, difficulty breathing, and swelling of the face, lips, tongue or other parts of the body, feeling unwell). This tends to be more severe in people, who suffer from allergies (especially asthma). For this reason, you should be monitored carefully for 30 minutes after each injection. If you get a reaction like this when you are not under medical supervision, contact your doctor or nearest hospital accident and emergency department immediately. Once you have had an allergic reaction like this, you should never be treated with Synacthen Depot or similar medicines again.
- bleeding of the adrenal gland (small glands above the kidneys) which may result in sudden pain in the stomach and back, weakness, fainting, loss of appetite and feeling or actually being sick
- blood clot (symptoms may include pain, swelling, redness, warmth and tenderness in the area of the clot depending on location in the body)
- blood in your stools
- blood in your urine
- blood in your vomit.

If you experience any of these at any time, tell your doctor straight away or go immediately to the nearest hospital accident and emergency department.

Side effects which may occur with Synacthen Depot include the following:

- menstrual (period) problems
- swelling of the face (moon face)
- increased thirst
- mood changes or fits
- decreased or blurred vision
- high blood pressure
- heart problems which can cause shortness of breath or ankle swelling
- inflammation of the blood vessels (sometimes with a rash, arthritis or kidney failure)
- itching
- inflammation of the pancreas which causes severe stomach and back pain
- acne, other skin problems or unusual bruising
- muscle cramps or pain, muscle weakness
- pain in back, hips, arms, shoulders or legs
- poor healing of wounds
- increased chance of infection
- abscess
- increase in the number of white blood cells which can cause bleeding, fever, infection or inflammation
- unusual increase in hair growth on body or face
- diabetes mellitus (increased sugar levels in your blood and urine)
- fluid retention
- sodium retention
- low levels of potassium which can cause muscle weakness, muscle twitching or abnormal heart beat or low levels of

calcium which can cause muscle cramps, stomach cramps or spasms. Your doctor may want to take a blood test to measure your blood levels of potassium or calcium
- increased appetite
- headache
- protrusion of the eye-balls in their sockets
- glaucoma/blurred vision
- thinning of skin
- a feeling of dizziness or "spinning"
- stomach pain or a bloated stomach
- inflammation of the gullet (food pipe)
- small, round, dark red spots on the skin
- bruising
- facial flushing
- darkening or lightening of skin colour
- increased sweating
- bone thinning and fractures of the bones
- hormonal imbalance
- ruptured tendon, the symptoms of which include severe pain, inability to use the affected arm or leg and rapid bruising at the site
- slowing of the rate of growth in children
- weight increase

- long term use in children up to 5 years may cause changes to the heart
- may affect the results of skin prick test reactions.

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme by connecting to the following website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Synacthen Depot

Synacthen Depot will be stored in the hospital pharmacy.

Keep out of the sight and reach of children.

Do not use Synacthen Depot after the expiry date which is stated on the ampoule and the carton. The expiry date refers to the last day of that month after EXP.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help protect the environment.

6. Contents of the pack and other information

What Synacthen Depot contains

The active substance of Synacthen Depot is tetracosactide (as acetate) 1 mg per ampoule.
The other ingredients are zinc chloride anhydrous pure, disodium phosphate dodecahydrate, sodium chloride, sodium hydroxide and water for injections.

What Synacthen Depot looks like and contents of the pack
Synacthen Depot is a sterile, milky white suspension in a 1 mL (millilitre) clear glass ampoule. Synacthen Depot comes in packs of 1 ampoule and 10 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kindom

Manufacturer:

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom

Misom Labs Limited, Malta Life Sciences Park, LS2.01.06 Industrial Estate, San Gwann, SGN 3000, Malta

The information in this leaflet applies only to Synacthen Depot. If you have any questions or you are not sure about anything, ask your doctor or a nurse.

This leaflet was last revised in: January 2025.

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The following information is intended for healthcare professionals only:

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.

1. Dosage

Indication	Method of administration
Therapeutic use:	Initially, daily doses of Synacthen Depot should be given but after approximately 3 days, intermittent doses may be given.
Adults:	Initially 1mg intramuscularly daily or 1mg every 12 hours in acute cases. After the acute symptoms of the disease have disappeared, treatment may be continued at a dose of 1mg every 2 to 3 days; in patients who respond well, the dosage may be reduced to 0.5mg every 2 to 3 days or 1mg per week.
Children aged 3 to 5 years:	Initially 0.25 to 0.5mg administered intramuscularly daily; the maintenance dose is 0.25 to 0.5mg every 2 to 8 days.
Children aged 5 to 12 years:	Initially 0.25 to 1mg administered intramuscularly daily; the maintenance dose is 0.25 to 1mg every 2 to 8 days.
Elderly:	There is no evidence to suggest that dosage should be different in the elderly.
Diagnostic use:	In cases of suspected adrenocortical insufficiency, where the 30-minute diagnostic test with Synacthen ampoules (see Synacthen Ampoules Summary of Product Characteristics) has yielded inconclusive results or where it is desired to determine the functional reserve of the adrenal cortex, a 5-hour test with Synacthen Depot may be performed.
Adults:	This test is based on measurement of the plasma cortisol concentration before and exactly 30 minutes, 1, 2, 3, 4 and 5 hours after an intramuscular injection of 1mg Synacthen Depot. If adrenocortical function is normal, baseline plasma

<table>
<tr><td></td><td>cortisol (normally >200 nmol/L) doubles in the first hour and then continues to rise slowly, as follows:

Table Hourly cortisol levels:
<table><tr><th>Time</th><th>nmol/L</th></tr><tr><td>1st hour</td><td>600 - 1250 nmol/L</td></tr><tr><td>2nd hour</td><td>750 – 1500 nmol/L</td></tr><tr><td>3rd hour</td><td>800 – 1550 nmol/L</td></tr><tr><td>4th hour</td><td>950 – 1650 nmol/L</td></tr><tr><td>5th hour</td><td>1000 – 1800 nmol/L</td></tr></table>
If plasma cortisol rises more slowly than indicated above, this may be the result of Addison's disease, secondary adrenocortical insufficiency due to a disorder of hypothalamo-pituitary function, or overdose of corticosteroids.

A 3-day test with Synacthen Depot may be used to differentiate between primary and secondary adrenocortical insufficiency.

All the plasma samples should be stored in a refrigerator until plasma cortisol level estimation.</td></tr>
<tr><td>Children:</td><td>No paediatric dosage has been established.</td></tr>
<tr><td>Elderly:</td><td>There is no evidence to suggest that dosage should be different in the elderly.</td></tr>
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2. Storage

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

3. Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.