

Synacthen® Depot

tetracosactide (tetracosactrin)

Consumer Medicine Information

What is in this leaflet

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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Synacthen Depot is used for

Synacthen Depot has two very different uses:

- It is used in people with multiple sclerosis who are experiencing a worsening of their symptoms

- It is used in young children to treat some types of seizure (fit), such as infantile spasms.

Synacthen Depot works by causing the adrenal glands to increase the production of natural "steroid" hormones that can help to reduce the symptoms of certain diseases.

This medicine is not suitable for newborn babies, especially if they are premature, because it contains benzyl alcohol, which can cause severe side effects in very young babies. It must also be used with caution in children up to 3 years of age.

Ask your doctor if you have any questions about why Synacthen Depot has been prescribed.

Your doctor may have prescribed it for another reason.

Synacthen Depot is available only with a doctor's prescription. It is not habit forming.

Before you have Synacthen Depot

When you must not have it

Do not have Synacthen Depot if you have an allergy to:

- tetracosactide (tetracosactrin), the active ingredient in Synacthen Depot
- any of the ingredients listed at the end of this leaflet.
- a similar medicine called ACTH or corticotrophin

Some of the symptoms of an allergic reaction may include:

- redness or pain at the injection site
- rash, itching, hives or flushing of the skin
- dizziness
- nausea (feeling sick) or vomiting
- difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Do not have Synacthen Depot if you have any of the following health problems/medical conditions:

- a viral illness or you have recently been vaccinated with a live virus vaccine
- an infection, unless you are taking antibiotics for it
- a stomach ulcer
- severe heart disease
- abnormal functioning of your adrenal glands
- a mental illness with disturbances in thinking, feelings and behaviour

If you are unsure whether any of the above conditions apply to you, your doctor can provide more information.

Do not have Synacthen Depot if you are pregnant.

It may affect your developing baby or cause a miscarriage if you have it during pregnancy.

Do not breast-feed if you are having Synacthen Depot.

There is not enough information to recommend breast-feeding while you are having this medicine.

Do not have Synacthen Depot after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should have this medicine, talk to your doctor.

Before you start to have it

Tell your doctor if you have asthma or allergies to other medicines, foods, dyes or preservatives.

Your chance of having an allergic reaction to Synacthen Depot may be greater than normal.

Tell your doctor if you have or have had any of the following medical conditions:

- diabetes
- high blood pressure
- kidney problems

- an inflammation of the bowel (e.g. ulcerative colitis or diverticulitis)
- recent bowel surgery
- blockage of a blood vessel by a clot (thromboembolism)
- weak brittle bones (osteoporosis)
- myasthenia gravis, a condition which causes extreme muscle weakness
- an underactive thyroid gland
- cirrhosis of the liver
- tuberculosis
- an eye infection caused by herpes simplex virus
- an infection caused by an amoeba

If you are unsure about any of the above conditions, your doctor can provide more information.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Synacthen Depot may interfere with each other. These include medicines used to treat:

- diabetes
- high blood pressure
- convulsions

It may be necessary to change the dose or in some cases stop the medicine while you are being treated with Synacthen Depot.

If you have not told your doctor about any of these things, tell him/her before you have Synacthen Depot.

How Synacthen Depot is given

How much is given

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

For seizures in children: the starting dose is usually a single daily injection ranging from 0.25 to 1mg, depending on the age of the child. Once the condition has improved, the number of injections can usually be reduced to one every 2 to 8 days.

How long treatment lasts

Synacthen Depot will not cure your condition but it may relieve some of the symptoms. The injections can be continued for as long as they provide a benefit. When

treatment is stopped, it will usually be done gradually to help maintain the normal function of your adrenal glands.

While you are having Synacthen Depot

Things you must do

If you become pregnant while having this medicine, tell your doctor immediately.

This medicine must not be used during pregnancy.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check for unwanted side effects. Some side effects such as change in blood pressure and in levels of sugar and other elements in the blood may only be found by doing regular tests. time to time to make sure the medicine is working and to prevent unwanted side effects. Children may need to have their heart checked and their growth monitored during long-term treatment.

If you suffer an injury requiring medical attention or are going to have surgery either during treatment with Synacthen Depot or within 1 year after treatment has stopped, tell the doctor, surgeon or anaesthetist about this medicine.

Prolonged treatment with Synacthen Depot may make your adrenal glands less able to cope with the stress to your body caused by an injury or surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Synacthen Depot.

Tell any other doctors, dentists, and pharmacists who treats you that you are having this medicine.

Things you must not do

Do not have any vaccinations without first checking with your doctor.

This medicine can change your response to vaccines and may prevent you from being successfully vaccinated against some diseases.

Do not take Synacthen Depot to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they seem to have the same condition as you.

Things to be careful of

Be careful driving or operating machinery or doing jobs that require you to be alert until you know how Synacthen Depot affects you.

This medicine may cause headache and vertigo (spinning sensation) in some people. Make sure you know how it affects you before you drive or do anything else that could be dangerous.

If you are being treated for diabetes, be careful to check your blood sugar regularly and report any problems to your doctor.

Synacthen Depot may change how well your diabetes is controlled. The dose of your diabetes medicines may need to be changed.

Be careful to avoid close contact with anyone who has an infectious disease.

This medicine may make you more susceptible to infections than usual and these infections may be more serious.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Synacthen Depot.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Side effects can often be relieved by reducing the dose given at each injection or increasing the time between injections.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

During the injection of Synacthen Depot, tell your doctor immediately if you notice any of the following signs of a possible allergic reaction:

- redness or pain at the injection site
- rash, itching, hives or flushing of the skin
- dizziness
- nausea (feeling sick) or vomiting
- difficulty breathing
- swelling of the face, lips, tongue or any other parts of the body

Allergic reactions can happen rarely, usually within 30 minutes after the injection. During this period, your doctor or nurse will watch you closely for signs of allergy and will have medicines to treat this type of reaction near at hand.

Tell your doctor immediately if you notice any of the following symptoms at any time during treatment:

- severe pain or tenderness in the stomach, which may be accompanied by nausea (feeling sick) and vomiting
- vomiting blood or material that looks like coffee grounds
- pain and ulceration along the food pipe leading from the throat to the stomach
- convulsions (fits)

- pain in the eye or difficulty seeing
- sudden severe headache, sudden loss of coordination, slurred speech, numbness in the arm or leg, pain in the calves, thighs or chest
- shortness of breath and swelling of the legs or ankles due to fluid build up
- rapid change in mood from extreme happiness to depression, personality changes or other disturbances in thinking, feelings and behaviour
- any infectious abscesses or wounds other than of a very minor nature
- difficulty urinating or passing little or no urine

Tell your doctor if any of the following happen and they worry you:

- headache
- spinning sensation (vertigo)
- difficulty sleeping
- muscle weakness
- feeling of bloating in the abdomen
- changes to the skin such as thinning, darkening in colour, acne, stretch marks, red or purple pin head spots or bruising

- red or moon-shaped face
- increased sweating
- excessive hair growth
- changes in menstrual period
- increased appetite
- weight gain

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Synacthen Depot

Storage

If you are storing Synacthen Depot at home, keep it in the fridge. Make sure that young people cannot reach it.

Disposal

If your doctor stops your treatment with Synacthen Depot or you find that the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Synacthen Depot is available in a glass ampoule containing 1 mL of milky white liquid; one ampoule per carton.

Ingredients

Each ampoule of Synacthen Depot contains 1 mg of the active ingredient, tetracosactide (tetracosactrin) (in a zinc phosphate complex). It also contains;

- benzyl alcohol
- hydrochloric acid
- sodium chloride
- sodium hydroxide
- sodium phosphate dibasic
- zinc chloride
- water for injections

Sponsor

Synacthen Depot is supplied in Australia by:

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173

Australia

Free Call Australia: 1800 899 005

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