

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tetracosactide Acetate 250 micrograms/ml solution for injection

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.
- The name of this medicine is Tetracosactide Acetate 250 micrograms/ml solution for injection but will be referred to as Tetracosactide Acetate throughout this leaflet.

What is in this leaflet

1. What Tetracosactide Acetate is and what it is used for
2. What you need to know before you are given Tetracosactide Acetate
3. How to use Tetracosactide Acetate
4. Possible side effects
5. How to store Tetracosactide Acetate
6. Contents of the pack and other information

1. WHAT TETRACOSACTIDE ACETATE IS AND WHAT IT IS USED FOR

Tetracosactide Acetate 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.

Tetracosactide Acetate is 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 TETRACOSACTIDE ACETATE

You should not be given Tetracosactide Acetate if:

- you are allergic (hypersensitive) to adrenocorticotropic hormone (ACTH), tetracosactide acetate or any of the other ingredients of Tetracosactide Acetate Ampoules (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 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 properly)

If any of the above applies to you, or if you are not sure, speak to your doctor or nurse before you are given Tetracosactide Acetate.

Warnings and Precautions

Before you are given Tetracosactide Acetate tell your doctor or nurse if:

- you suffer from high blood pressure
- you suffer from thromboembolism (blood vessel blocked by a blood clot)
- you suffer from myasthenia gravis (extreme muscle weakness)
- you suffer from osteoporosis (thinning of the bones)
- you suffer from an inflammation of the bowel (e.g. ulcerative colitis or diverticulitis)
- you have been recently vaccinated
- you have a severe liver disease (cirrhosis)
- you have a reduced immune system
- you are pregnant, think you might be pregnant or are breast feeding
- you have ocular herpes simplex (viral infection of the eye)
- you have kidney problems.

Other medicines and Tetracosactide Acetate

Tell your doctor or nurse if you are taking/using or have recently taken/used any of the following medicines as they may interfere with Tetracosactide Acetate:

- medicines to control high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan)
- medicines to control diabetes such as insulin or metformin
- corticosteroids (medicines used to treat inflammatory conditions in your body such as asthma or arthritis)
- 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.

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 Tetracosactide Acetate during pregnancy. Tetracosactide Acetate 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 Tetracosactide Acetate, do not drive or operate machinery until these effects have worn off.

Important information about some of the ingredients of Tetracosactide Acetate Ampoules

Tetracosactide Acetate Ampoules contain less than 1 mmol sodium (23mg) per 1mg, i.e. is essentially 'sodium-free'.

3. HOW TO USE TETRACOSACTIDE ACETATE

Your treatment with Tetracosactide Acetate will take place in a hospital, under the supervision of a doctor. The doctor will be monitoring your progress carefully during your treatment with Tetracosactide Acetate.

The liquid will be drawn up into a syringe and injected into a muscle or vein by your doctor or nurse. You will be given a single injection of Tetracosactide Acetate. You will have two blood samples taken, one before the injection of Tetracosactide Acetate and the other 30 minutes after injection. These blood samples will show whether your adrenal glands are functioning as well as they should.

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

Children will be given a lower dose based on their age and weight.

What to do if you think you have received more Tetracosactide Acetate 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 Tetracosactide Acetate

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, Tetracosactide Acetate 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 very unwell). This tends to be more severe in people, who suffer from allergies (especially asthma). For these reasons, you should be monitored carefully for 30 minutes after the injection. If you have had an allergic reaction, you should never be treated with Tetracosactide Acetate or similar medicines again.
- bleeding into the adrenal gland (small glands above the kidneys) which may result in sudden stomach or back pain, 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 Tetracosactide Acetate include the following:

- allergic reaction with skin irritation and swelling
- 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)
- inflammation of the pancreas which causes severe stomach and back pain
- feeling or actually being sick
- general feeling of being unwell
- acne, other skin problems or unusual bruising
- muscle cramps or pain, muscle weakness
- pain in back, hips, arms, shoulders or legs
- itching
- 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
- thinning of the skin
- may affect the results of skin prick test reactions
- 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
- 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
- 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.

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, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects you can help provide more information on the safety of this medicine.

The following information is intended for medical or healthcare professionals only:

1. Dosage

Indication	Method of administration
Adults:	<p>This preparation of Tetracosactide Acetate is intended for administration for diagnostic purposes only as a single intramuscular or intravenous dose; it is not to be used for repeated therapeutic administration.</p> <p>The 30-minute Tetracosactide Acetate diagnostic test: This test is based on measurement of the plasma cortisol concentration immediately before and exactly 30 minutes after an intramuscular or intravenous injection of 250micrograms (1ml) Tetracosactide Acetate. Adrenocortical function can be regarded as normal if the post injection rise in plasma cortisol concentration increased by 200nmol/litre (70 micrograms/litre), i.e. if the value 30 minutes after injection is >500nmol/litre (180 micrograms/litre), adrenocortical function is regarded as normal. All the plasma samples should be stored in a refrigerator until plasma cortisol level estimation.</p> <p>Where the 30-minute test has yielded inconclusive results, or where it is desired to determine the functional reserve of the adrenal cortex, a 5-hour test can be performed with Synacthen Depot (see separate Summary of Product Characteristics). Furthermore, a 3-day test with Synacthen Depot may be used to differentiate between primary and secondary adrenocortical insufficiency.</p>
Children:	<p>An intravenous dose of 250micrograms/1.73m² body surface area has been suggested. Thus for children aged 5 to 7 years, approximately half the adult dose will be adequate. For more accurate dosing of other ages, standard body surface area tables should be consulted.</p>
Elderly:	<p>There is no evidence to suggest that dosage should be different in the elderly.</p>

2. Disposal

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

3. Overdose

Overdosage is unlikely to be a problem when the product is used as a single dose for diagnostic purposes.

4. Storage

Tetracosactide Acetate should be protected from light and stored in a refrigerator (2 - 8°C).

5. HOW TO STORE TETRACOSACTIDE ACETATE

- **Keep out of the sight and reach of children.**
- Tetracosactide Acetate Ampoules will be stored in the hospital pharmacy.
- Store in a refrigerator (2°C-8°C).
- Store in the original carton in order to protect from light
- After opening: the product must be used immediately.
- Do not use this medicine after the expiry date which is stated on the ampoule and the box after "EXP". The expiry date refers to the last day of that month.
- If your solution becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Tetracosactide Acetate Ampoules contain

Each 1 ml ampoule contains 250 micrograms tetracosactide acetate in aqueous solution. Each ampoule also contains acetic acid, sodium acetate, sodium chloride and water for injection

What Tetracosactide Acetate looks like and contents of the pack

Tetracosactide Acetate is a clear, colourless sterile liquid that comes in a 1 ml (millilitre) clear glass ampoule.

Tetracosactide Acetate comes in packs of 1 ampoule.

Manufactured by
DOPPEL FARMACEUTICI, VIA VOLTURNO, 48, 20089 ROZZANO,
(MILAN), ITALY.

ALFASIGMA S.P.A., VIA PONTINA KM 30,400, 00071 POMEZIA, ITALY.

Procured from within the EU. Repackaged by the Product Licence holder:
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way,
Aldridge, Walsall, WS9 8ER.

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

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To request a copy of this leaflet in
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01922 745645 and ask for the
Regulatory Department.