Source : Medicines Org UK

Package leaflet: Information for the user

Terlipressin acetate 0.12 mg/ml solution for injection

terlipressin (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 Terlipressin acetate 0.12 mg/ml solution for injection is and what it is used for

Terlipressin acetate 0.12 mg/ml solution for injection is a synthetic pituitary hormone.

Terlipressin acetate 0.12 mg/ml solution for injection is used for treatment of bleeding from dilated veins in the food pipe leading to your stomach (bleeding oesophageal varices).

2. What you need to know before you are given Terlipressin acetate 0.12 mg/ml solution for injection

You should not be given Terlipressin acetate 0.12 mg/ml solution for injection
- if you are allergic to terlipressin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
This medicine will be given to you if you have severe or life-threatening bleeding in your food pipe (oesophagus). It is used under continuous monitoring of your heart and blood circulation.
If you are able to, tell your doctor if you suffer from the conditions shown below:
- if you are suffering from a severe infection known as septic shock
- if you suffer from bronchial asthma or other conditions that affect your breathing
- if you suffer from acute coronary syndrome (ACS describes symptoms related to poor blood flow to the heart muscle leading to a heart attack. This results in chest pain, or angina pectoris.)
- if you suffer from uncontrolled high blood pressure, insufficient blood circulation in the heart vessels (e.g. angina), have previously had a heart attack (myocardial infarction), or you have hardening of your arteries (arteriosclerosis)
- if you suffer from irregular heartbeats (cardiac arrhythmias)
- if you have poor blood circulation to your brain (e.g. you have had a stroke) or to your limbs (peripheral vascular disease)
- if you suffer from impaired kidney function (renal insufficiency)
- if you suffer from disturbances in the level of salt (electrolytes) in your blood
- if you are suffering from reduced amount of fluid in your circulation or have already lost a large amount of blood
- if you are over the age of 70 years
- if you are pregnant.

Children and adolescents
Terlipressin acetate 0.12 mg/ml solution for injection is not recommended for use in children and adolescents due to insufficient experience.

Other medicines and Terlipressin acetate 0.12 mg/ml solution for injection
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.
Please inform your doctor immediately if you use the following medicines:
- drugs that have an effect on your heart rate (e.g. beta-blockers or propofol)
- drugs that can trigger irregular beating of the heart (arrhythmia) such as the following:
  - anti-arrhythmic drugs known as Class IA (quinidine, procainamide, disopyramide) and Class III (amiodarone, sotalol, ibutilide, dofetilide)
  - an antibiotic called erythromycin
  - antihistamines (mainly used to treat allergies but also found in certain cough and cold remedies)
  - medicines used to treat depression called tricyclic antidepressants
  - medicines that may alter the level of salt or electrolytes in your blood, particularly diuretics (used to treat high blood pressure and heart failure).

Pregnancy and breast-feeding
Terlipressin acetate 0.12 mg/ml solution for injection should only be used during pregnancy if it is vital to treat your condition. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

It is not known if Terlipressin acetate 0.12 mg/ml solution for injection is present in breast milk. Therefore the possible effects on your baby are unknown. You should discuss the potential risk to your baby with your doctor.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. However, if you feel unwell after receiving the injection, do not drive or operate machinery.

Terlipressin acetate 0.12 mg/ml solution for injection contains sodium
This medicinal product contains 15.7 mmol (or 361 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. How Terlipressin acetate 0.12 mg/ml solution for injection is used

This medicine will always be administered to you by your doctor. Please ask your doctor for further information regarding its use.

How much Terlipressin acetate 0.12 mg/ml solution for injection is given

Adults
Initially 1-2 mg terlipressin acetate (equivalent to 8.5-17 ml of injection solution) is given by injection into your vein. Your dose will depend on your body weight.
After the initial injection, your dose may be reduced to 1 mg terlipressin acetate (equivalent to 8.5 ml of solution), every 4 to 6 hours.

The maximum dose you can receive each day is approximately 120 micrograms/kg body weight.

Elderly
If you are over 70 years of age speak with your doctor before you receive Terlipressin acetate 0.12 mg/ml solution for injection.

How Terlipressin acetate 0.12 mg/ml solution for injection is given
Terlipressin acetate 0.12 mg/ml solution for injection should be slowly injected intravenously.

How often you will be given Terlipressin acetate 0.12 mg/ml solution for injection
The use is limited to 2 – 3 days, depending on the course of your condition.

If you are given more Terlipressin acetate 0.12 mg/ml solution for injection than you should be
You must not have more Terlipressin acetate 0.12 mg/ml solution for injection than the recommended dose. If you are given too much then you may have a rapid increase in your blood pressure, especially if you already suffer with high blood pressure. If this happens then you need another medicine called an alpha blocker (e.g. clonidine) to control your blood pressure.

If you experience lightheadedness, dizziness, or feeling faint, tell your doctor as these could be signs of a low heart rate. This can be treated with a medicine called atropine.

Terlipressin acetate 0.12 mg/ml solution for injection

terlipressin (as acetate)

The following information is intended for healthcare professionals only:

INFORMATION FOR THE HEALTHCARE PROFESSIONALS

Please see the Summary of Product Characteristics for more information.

Administration of Terlipressin acetate 0.12 mg/ml solution for injection
The administration of terlipressin serves the emergency care for acute bleeding oesophageal varices until endoscopic therapy is available. Afterwards the administration of terlipressin for the treatment of oesophageal varices is usually an adjuvant therapy to the endoscopic haemostasis.

Adults
The recommended initial dose is 1 to 2 mg terlipressin acetate# (equivalent to 8.5 to 17 ml of solution), administered by intravenous injection over a period of time.

Depending on the patient's body weight the dose can be adjusted as follows:
- weight less than 50 kg: 1 mg terlipressin acetate (8.5 ml)
- weight 50 kg to 70 kg: 1.5 mg terlipressin acetate (12.75 ml)
- weight exceeding 70 kg: 2 mg terlipressin acetate (17 ml).

After the initial injection, the dose can be reduced to 1 mg terlipressin acetate every 4 to 6 hours.

The approximate value for the maximum daily dose of Terlipressin acetate 0.12 mg/ml solution for injection is 120 µg terlipressin acetate per kg body weight.

The therapy is to be limited to 2 – 3 days in adaptation to the course of the disease.

1 to 2 mg terlipressin acetate corresponding to 0.85 to 1.7 mg terlipressin.

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If you forget to use Terlipressin acetate 0.12 mg/ml solution for injection
You will be given Terlipressin acetate 0.12 mg/ml solution for injection in hospital under the supervision of your doctor.

If you stop using Terlipressin acetate 0.12 mg/ml solution for injection
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects or signs you should pay attention to, and measures to be taken if you are affected
In very rare cases severe side effects are possible when you are given terlipressin. If you are affected by one of the following side effects, please tell your doctor immediately if you are able to. Your doctor should not give you any more terlipressin.

Severe shortness of breath due to an asthma attack, severe difficulty with or stopping breathing, severe pain in the chest (angina), severe and persistent irregular heartbeats, locally dead skin (necrosis), convulsions (seizure), kidney failure.

Other possible side effects
Common (may affect up to 1 in 10 people)
- headache
- too slow heart rate
- signs of insufficient blood circulation in the heart vessels shown in the ECG
- high blood pressure
- low blood pressure
- insufficient blood circulation in arms, legs and skin, pale skin
- abdominal cramps
- diarrhoea.

Uncommon (may affect up to 1 in 100 people)
- too little sodium in the blood (hyponatraemia) if not monitored
- dead skin (necrosis) not related to the injection site
- rapid increase in blood pressure
- too fast heart rate (palpitations)
- swelling of the tissues in the body or fluid on the lungs
- chest pain
- heart attack
- excess fluid on the lungs
- heart failure (Torsade de Pointes)
- insufficient blood flow to the intestines
- uterine cramps
- decreased blood flow to the uterus
- bluish colouration of the skin or lips
- hot flushes
- temporary nausea (feeling sick)
- temporary vomiting
- inflammation of the lymph vessels (fine red streaks under your skin extending from the affected area to the armpit or groin and by fever, chills, headache, and muscle pain).

Rare (may affect up to 1 in 1,000 people)
- shortness of breath.

Very rare (may affect up to 1 in 10,000 people)
- too much sugar in the blood (hyperglycaemia)
- stroke.

Not known (frequency cannot be estimated from the available data)
- uterine cramps (cramps in the womb)
- decreased blood flow to the uterus.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist 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 at: 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 Terlipressin acetate 0.12 mg/ml solution for injection

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator at 2-8˚C.

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

6. Contents of the pack and other information

What Terlipressin acetate 0.12 mg/ml solution for injection contains
- The active substance is terlipressin (as acetate). Each ampoule contains 1 mg of terlipressin acetate in 8.5 ml solution for injection, corresponding to 0.85 mg terlipressin. This is equivalent to 0.12 mg terlipressin acetate per ml, corresponding to 0.1 mg terlipressin per ml.
- The other ingredients are sodium acetate trihydrate, sodium chloride, acetic acid, glacial (for pH adjustment) and water for injection.

What Terlipressin acetate 0.12 mg/ml solution for injection looks like and contents of the pack
Terlipressin acetate 0.12 mg/ml solution for injection is a clear, colourless solution for injection without visible particles.
Terlipressin acetate 0.12 mg/ml solution for injection is packed into one carton with 5 ampoules.

Marketing Authorisation Holder
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Manufacturer
Sun Pharmaceutical Industries Europe B.V.
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124 Fabricii Street
400632, Cluj-Napoca
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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Terlipressinacetat SUN
Germany:	Terlipressin SUN 0,1 mg/ml Injektionslösung
Finland:	Terlipressin SUN 1 mg injektioneste, liuos
France:	Terlipressine SUN 0,12 mg/ml, solution injectable
Italy:	Terlipressina SUN 0,1 mg/ml soluzione iniettabile
The Netherlands:	Terlipressine SUN 0,1 mg/ml, oplossing voor injectie
Norway:	Terlipressin SUN 1 mg injeksjonsvæske, oppløsning
Spain:	Terlipresina SUN 1 mg solución inyectable EFG
Sweden:	Terlipressin SUN 1 mg injektionsvätska, lösning
United Kingdom:	Terlipressin acetate 0.12 mg/ml solution for injection

This leaflet was last revised in June 2021.

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Elderly
Terlipressin should only be used with caution in patients over 70 years.

Children and adolescents
Terlipressin is not recommended in children and adolescents due to insufficient experience on safety and efficacy.

Renal insufficiency
Terlipressin should only be used with caution in patients with chronic renal failure.

Hepatic insufficiency
A dose adjustment is not required in patients with liver failure.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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