Terlipressin Acetate 1 mg solution for injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you have any questions.
- Please pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:
1. What Terlipressin Acetate 1 mg solution for injection is and what it is used for
2. What you need to know before you use Terlipressin Acetate 1 mg solution for injection
3. How to use Terlipressin Acetate 1 mg solution for injection
4. Possible side effects
5. How to store Terlipressin Acetate 1 mg solution for injection
6. Contents of the pack and other information

1. What Terlipressin Acetate 1 mg solution for injection is and what it is used for

Terlipressin Acetate 1 mg solution for injection is a synthetic pituitary hormone (used to treat high blood pressure and heart failure).

Terlipressin Acetate 1 mg solution for injection is used to treat the following conditions shown below:
- Conditions that affect your breathing
- Severe or life threatening bleeding in your food pipe (oesophagus).
- Conditions that affect your blood circulation.
- Severe or life threatening bleeding from dilated (widening) veins in the food pipe (oesophagus).
- Other severe or life threatening bleeding (e.g. angina), have previously had a heart attack (cardiac arrythmias)
- To treat heart failure
- Conditions that affect your veins, for example, varicose veins
- To increase the amount of blood to the limbs
- Conditions that affect your kidneys
- To treat urinary tract infections
- For the temporary control of diarrhea
- For the temporary control of diarrhea

2. What you need to know before you start using Terlipressin Acetate 1 mg solution for injection

- If you are allergic to terlipressin or any of the other ingredients of Terlipressin Acetate 1 mg solution for injection (see section 4).
- If you have had an allergic reaction to a similar medicine.

Possible side effects

- Nausea
-漩涡
- Diarrhoea
- Headache
- Fainting
- Convulsions (seizure)
- In the very rare cases, there may be severe side effects.
- Severe and persistent irregular heart beats
- You may experience a low heart rate. This can be treated with a medicine called an alpha blocker (e.g. yohimbine). You may also experience a low blood pressure. This can be treated with a medicine called atropine.
- That the solution discolours.

The following information is intended for medicinal or healthcare professionals only

Terlipressin Acetate 1 mg solution for injection

There are no limitations.

Breastfeeding and breast-feeding
If you are breastfeeding, you should think you may be pregnant or planning to have a baby, ask your doctor or pharmacist if you can continue breastfeeding or if you should stop.

Ask your doctor or pharmacist for advice before taking any medicine.

Terlipressin Acetate 1 mg solution for injection should only be used during pregnancy if it is vital to treat your condition.

It is not known if Terlipressin Acetate 1 mg solution for injection can be found in breast milk, therefore it is not known if there may be an effect on your baby. You should discuss the potential risk to your baby with your doctor.

Driving and using machines
No special precautions are necessary. You are able to drive and use machines have been performed.

Terlipressin Acetate 1 mg solution for injection contains sodium

This medicine contains 3.8 mg sodium (equivalent to 0.15 mmol) in 1 ml of injection. This is equivalent to 0.03% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Terlipressin Acetate 1 mg solution for injection

This medicine is not to be used by yourself but will be administered to you by your doctor. Please ask your doctor for further information regarding its use.

Acute

The dose will be determined by the doctor depending on patient’s weight.

Initially, 1 to 2 mg Terlipressin Acetate 1 mg solution equivalent to 1 to 2 ampoules of Terlipressin Acetate 1 mg solution for injection will depend on your body weight.

After that, your injection may be reduced to 1 mg every 4 to 6 hours.

Dysfunctional bleeding
Terlipressin Acetate 1 mg solution for injection is administered. Your dose will depend on your body weight.

The following information is intended for medicinal or healthcare professionals only

Parenteral

Terlipressin Acetate 1 mg solution for injection should not be given to children and adolescents due to insufficient experience.

Method and route of administration

The recommended route of administration is a spray into and apply it directly on the skin.

The use of this medicine is limited to 2 – 3 days, depending on the condition.

If you use more Terlipressin Acetate 1 mg solution for injection than you should

If you are given too much then you may have a rapid heart rate. This can be treated with a medicine called atropine.

If you忘记 to use Terlipressin Acetate 1 mg solution for injection

If you are affected by any of the following side effects, please tell your doctor immediately.
- Taste, thirst or the bleeding in your food pipe (oesophagus).
- If you have had an allergic reaction to a similar medicine.
- Blood circulation.
- You may experience a low heart rate. This can be treated with a medicine called an alpha blocker (e.g. yohimbine). You may also experience a low blood pressure. This can be treated with a medicine called atropine.
- That the solution discolours.

The following information is intended for medicinal or healthcare professionals only

Initial injection

- Terlipressin Acetate 1 mg solution (equivalent to 1 to 2 ampoules of Terlipressin Acetate 1 mg solution for injection) are administered. Your dose will depend on your body weight.

Preparation of the injection:

- Any anti-viruses drugs known as Class IA (quinidine, propranolol, etc) also found in certain cough and cold remedies) and discolouration prior to administration.

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- Terlipressin Acetate 1 mg solution for injection is administered. Your dose will depend on your body weight.
Frequency of possible side effects:

Common (affects less than 1 in 10 people):

- Heart and circulation
  - very slow heart rate
  - signs of insufficient blood circulation in the heart vessels in the ECG
  - insufficient blood circulation in legs and skin
  - edema of face
  - pale skin

- General

- Stomach and gut

- Mind and nervous system

- triggering of a fit

Heart and circulation

- short-pain
- rapid increase in blood pressure
- irregular heart rate
- chest pain
- chest pain (palpitations)
- too fast heart rate (palpitations)
- bluish colouration of the skin or lips
- heart failure (Torsade de Pointes)
- hot flushes

Lungs and breathing

- excess fluid on the lungs
- shortness of breath due to spasm in the bronchial muscles
- severe difficulty with or stopping breathing

Stomach and gut

- temporary nausea
- temporary vomiting

General

- inflammation of the lymph vessels
- reduced blood supply to the intestinal system
- increased temperature
- increased blood flow to the uterus
- dead skin (erythroderma) not related to the injection site

Results of blood tests

- too little sodium in the blood (hyponatraemia)

Heart and circulation

- chest pain
- high or low blood pressure
- insufficient blood circulation in arms, legs and skin
- signs of insufficient blood circulation in legs and skin
- edema of face
- very slow heart rate
- signs of insufficient blood circulation in the heart vessels in the ECG

Uncommon (affects less than 1 in 100 people):

- Headache

Stomach and gut

- Temporary abdominal cramps
- Temporary diarrhoea
- abdominal cramps (in women)

Mind and nervous system

- triggering of a fit

Heart and circulation

- chest pain
- signs of insufficient blood circulation in the heart vessels in the ECG
- insufficient blood circulation in legs and skin
- edema of face
- pale skin

General

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Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the UK Yellow Card Scheme.

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 Terlipressin Acetate 1 mg solution for injection

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

Store in a refrigerator at 2-8˚C. Keep in the original package in order to protect from light.

Once opened the medicine should be used immediately.

Do not use this medicine if you notice

- that the solution discolours.

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 1 mg solution for injection contains

- The active substance is terlipressin acetate.

  Each ampoule contains: 1 mg of terlipressin-acetate in 8.5 ml solution for injection, corresponding to 0.85 mg terlipressin.

  1 ml of solution for injection contains 0.12 mg/ml of terlipressin-acetate, equivalent to 0.1 mg terlipressin.

- The other ingredients are:
  - sodium chloride, glacial acetic acid, sodium acetate and water for injection.

What Terlipressin Acetate 1 mg solution for injection looks like and contents of the pack

This medicine is presented as a solution for injection. It is supplied in clear, Type I glass ampoules containing 1 ml of solution for injection.

Each ampoule contains 8.5 ml of solution for injection.

Terlipressin Acetate 1 mg solution for injection is a clear, colourless solution for injection.

This medicine is available in pack sizes of:

One carton with 5 ampoules with 8.5 ml of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Fyln Pharma Ltd
Marine House
Clanwilliam Place
Dublin 2
Ireland

Manufacturer

Altran Pharmaceuticals, S.A.
Avda de la Constitución, 198-199
Polígono Industrial Monte Boyal
Casarrubios del Monte, 45950 Toledo
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Terlipressin Inresa 1 mg Injektionslösung

UK: Terlipressin Acetate 1 mg solution for injection

This leaflet was last revised in April 2021.