

PACKAGE LEAFLET INFORMATION FOR THE USER

Terlipressin Acetate AFT 0.12 mg/ml solution for injection

Read all of this leaflet carefully before you are given this medicine.

- 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.
- The full name of your medicine is Terlipressin Acetate AFT 0.12 mg/ml solution for injection. In this leaflet from here onwards it is called Terlipressin Acetate AFT.

In this leaflet:

1. What Terlipressin Acetate AFT is and what it is used for
2. Before you are given Terlipressin Acetate AFT
3. How you will be given Terlipressin Acetate AFT
4. Possible side effects
5. How Terlipressin Acetate AFT is stored
6. Contents of the pack and other information

1. WHAT TERLIPRESSIN ACETATE AFT IS AND WHAT IT IS USED FOR

Terlipressin Acetate AFT is a ready-to-use solution for injection containing the active substance, terlipressin acetate.

What Terlipressin Acetate AFT is used for

Terlipressin Acetate AFT is used to treat ‘bleeding oesophageal varices’.

- ‘Oesophageal varices’ are veins in your food pipe (oesophagus) that are enlarged because they have an increased blood flow. This is caused by liver problems.
- The increased blood flow can cause them to burst and bleed.

This is a serious and life-threatening problem.

How Terlipressin Acetate AFT works

When the medicine is injected into your bloodstream:

- The active ingredient (terlipressin acetate) is broken down to release a substance called “lysine vasopressin”.
- This substance acts on the walls of your blood vessels, causing them to narrow and decrease the blood flow to your affected veins.
- This helps to stop or slow the bleeding.

2. BEFORE YOU ARE GIVEN TERLIPRESSIN ACETATE AFT

You must not be given Terlipressin Acetate AFT if you:

- are **allergic (hypersensitive)** to terlipressin acetate or any of the other ingredients of Terlipressin-AFT, (listed in Section 6).
- are **pregnant**.

You must not be given Terlipressin Acetate AFT if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given Terlipressin Acetate AFT.

Warnings and Precautions

Please check with your doctor before Terlipressin Acetate AFT is given to you if you:

- have **high blood pressure (hypertension)**.
- have a **heart problem** such as an irregular heart beat.
- have **heart disease** such as where your heart’s arteries have become hardened, narrow or blocked. This means that your heart’s muscle is not getting enough blood supply (coronary insufficiency).
- have a **circulation problem (atherosclerosis)**. This is where fatty plaques have developed on the inner lining of your arteries and are stopping your blood from flowing normally.
- have **septic shock**. Septic shock is a serious condition that occurs when a major infection leads to low blood pressure and low blood flow.

If any of the above apply to you (or you are not sure) talk to your doctor or nurse before you are given Terlipressin Acetate AFT.

Using other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. Terlipressin Acetate AFT can affect the way some other medicines work. Also, some other medicines can affect the way Terlipressin Acetate AFT works.

Please inform your doctor immediately if you take any of the following medicines:

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)
- erythromycin (an antibiotic)
- antihistamines (mainly used to treat allergies but also found in certain cough and cold remedies)
- tricyclic antidepressants used to treat depression
- medicines that may alter the level of salt or electrolytes in your blood, particularly diuretics (water tablets used to treat high blood pressure and heart failure).

Pregnancy and breast-feeding

- You must not be given Terlipressin Acetate AFT if you are pregnant or breast-feeding. It is not known if Terlipressin Acetate AFT passes into the mother’s milk.

Ask your doctor, nurse or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

3. HOW YOU WILL BE GIVEN TERLIPRESSIN ACETATE AFT

Terlipressin Acetate AFT is used in hospitals and will be given to you by a doctor or nurse.

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Terlipressin Acetate AFT will be given to you as an injection into a vein.

- The usual starting dose is 2 milligrams (mg).
- Your doctor may then give you 1 to 2 mg every 4 to 6 hours until the bleeding has been controlled.
- Your treatment could last up to a maximum of 48 hours.

During treatment, your blood pressure, serum sodium and potassium and fluid balance will be monitored closely.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Terlipressin Acetate AFT can cause side effects, although not everybody gets them.

Commonly reported side effects (affect less than 1 in 10 people):

- Headache
- Raised blood pressure, very slow heart rate
- Stomach pains, cramps or diarrhoea
- Skin becoming white which usually goes away after a short time (transient blanching)

Uncommon reported side effects (may affect up to 1 in 100 people):

- Heart failure, rare form of rapid heartbeat (Torsade de pointes)
- Skin damage
- Uterine cramps
- Decreased blood flow to the uterus
- Low sodium in the blood
- Irregular or rapid heartbeat, palpitations, chest pain, heart attack
- Fluid in the lungs, severe breathing problems
- Bluish discoloration of the skin and mucous membranes
- Hot flush
- Feeling or being sick
- Skin damage at the injection site
- Muscle weakness and twitching (symptoms of hyponatraemia)
- Frequent forceful bowel movements, blood in stools (symptoms of intestinal ischaemia)

Rare cases (may affect up to 1 in 1,000 people):

- Difficulty breathing

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. 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.

5. HOW TERLIPRESSIN ACETATE AFT IS STORED

Keep out of the sight and reach of children. Do not use Terlipressin Acetate AFT after the expiry date which is stated on the pack.

The expiry date refers to the last day of that month. Store in a refrigerator at 2-8 °C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Terlipressin Acetate AFT contains

- The active substance is terlipressin acetate. Each ampoule contains 1 mg terlipressin acetate in 8.5 ml solution for injection. This is equivalent to 0.12 mg terlipressin acetate per ml.
- The other ingredients are sodium chloride, acetic acid, sodium acetate and water for injection.

What Terlipressin Acetate AFT looks like

Terlipressin Acetate AFT is a clear, colourless solution for injection.

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