#### Terlipressin Cas No. : 14636-12-5

Terlipressin is a medicine similar to a naturally occurring hormone present in the body, known as antidiuretic hormone (ADH) or vasopressin. ADH has two main effects in the body. Firstly, it causes narrowing of blood vessels (vasoconstriction), thereby limiting blood flow to a particular area of the body. It also acts on receptors in the kidney to retain water in the body, which helps to prevent excessive loss of water in the urine.

Active Pharmaceuticals Ingredients Manufacturers



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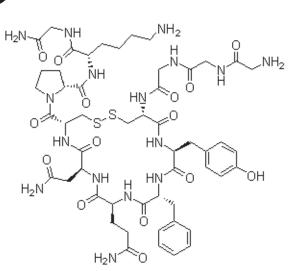
# Taj Pharmaceuticals Ltd. Terlipressin CAS No. : 14636-12-5

#### Identifiers

Molecular Formula C52H74N16O15S2 Molecular Weight 1227.37 CAS Registry Number 14636-12-5

#### **Synonyms**

N-(N-(N-Glycylglycyl)glycyl)-8-L-lysinevasopressin; (2S)-1-[(4S,7S,10S,13S,16S,19S)-19-[[2-[[2-[ (2-Aminoacetyl)amino]acetyl]amino]-13-benzyl-10-(2-carbamoylethyl)-7-(carbamoylmethyl)-16-[(4-hydroxyphenyl)methyl]-6,9,12,15,18-pentaoxo-1, 2-dithia-5,8,11,14,17-pentazacycloicosane-4-carbonyl]-N-[(1S)-5-amino-1-(carbamoylmethylcarbamoyl)pentyl] pyrrolidine-2-carboxamide)



### DOSAGE

To get the most benefit from your medicine, take it exactly as prescribed. You should also take care to look after your medicine.

This medicine may be available from different manufacturers and in several different forms and so you should check the Patient Information Leaflet or the medicine label for exact details on when and how to take it and how to look after it. Terlipressin is an injection that is usually given by a healthcare professional.

The person responsible for giving you your medicine will make sure that you get the right dose.

If you feel that the medicine is making you feel unwell or you think it is not working, you should talk to someone who is involved in your care. Terlipressin is similar to a chemical called vasopressin which is found in the body.

Terlipressin decreases the blood flow to the gastrointestinal system and can help to reduce gastrointestinal bleeding caused by high blood pressure in the liver or swollen blood vessels in the oesophagus.

#### **SIDE EFFECTS**

Some people receiving Terlipressin have had an immediate reaction to the medication. Tell your caregiver right away if you feel weak, nauseated, light-headed, sweaty, or have a fast heartbeat, chest tightness, or weak breathing just after receiving Terlipressin . Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Tell your caregivers at once if you have any of these serious side effects:

\*slow or uneven heart rate;

- \*gasping or trouble breathing;
- \*chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, general ill feeling;
- \*tingling or loss of feeling in your hands or feet;
- \*skin changes or discoloration;
- \*swelling, rapid weight gain;



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\*feeling light-headed, fainting; or \*severe nausea or stomach pain.

Less serious side effects may be more likely to occur, such as:

\*mild stomach pain, bloating, or gas; \*dizziness; or \*throbbing headache.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

## PRECAUTIONS

Individuals taking this medicine should be monitored for changes in blood pressure. - It is recommended that individuals taking this medicine have their fluid and salt (electrolyte) balance monitored regularly.

Not to be used in

- Pregnancy

This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such an allergy. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

Pregnancy and Breastfeeding

Certain medicines should not be used during pregnancy or breastfeeding. However, other medicines may be safely used in pregnancy or breastfeeding providing the benefits to the mother outweigh the risks to the unborn baby. Always inform your doctor if you are pregnant or planning a pregnancy, before using any medicine.

## **INTERACTION**

The following drugs may potentiate the antidiuretic effect of Terlipressin when used concurrently: carbamazepine; chlorpropamide; clofibrate; urea; fludrocortisone; tricyclic antidepressants.

The following drugs may decrease the antidiuretic effect of Terlipressin when used concurrently: demeclocyline; norepinephrine; lithium; heparin, alcohol.

Ganglionic blocking agents may produce a marked increase in sensitivity to the pressor effects of Terlipressin .

Diabetes Insipidus, Asystole, Postoperative Gas Pains, Abdominal Distension Prior to Abdominal X-ray, Esophageal Varices with Bleeding



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### **DRUG DESCRIPTION**

Terlipressin as vasoactive drug used for the management of hypotension. It has been found to be effective when norepinephrine does not help.

Indications for use include norepinephrine-resistant septic shock and hepatorenal syndrome. In addition, it is used in bleeding oesophageal varices.

Terlipressin is an analogue of vasopressin used as a vasoactive drug in the management of hypotension. It has been found to be effective when norepinephrine does not help.

Terlipressin is a medicine similar to a naturally occurring hormone present in the body, known as antidiuretic hormone (ADH) or vasopressin. ADH has two main effects in the body. Firstly, it causes narrowing of blood vessels (vasoconstriction), thereby limiting blood flow to a



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particular area of the body. It also acts on receptors in the kidney to retain water in the body, which helps to prevent excessive loss of water in the urine.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009



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