

## **Package leaflet: Information for the patient**

### **Oxyptadil® Injection for Intravenous Infusion**

Aviptadil injection 150mcg/10mL

**Read all of this leaflet carefully before you start taking 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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

- 1. What Oxyptadil® is and what it is used for**
- 2. What you need to know before you take Oxyptadil®**
- 3. How to take Oxyptadil®**
- 4. Possible side effects**
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#### **1. What Oxyptadil® is and what it is used for**

This medicine contains Aviptadil. Aviptadil is a synthetic form of human Vasoactive Intestinal Polypeptide (VIP). VIP is highly concentrated in the lung and reduces lung inflammation. It is used to treat Acute Respiratory Distress Syndrome (ARDS). ARDS is a life-threatening lung injury that allows fluid to leak into the lungs. Breathing becomes difficult and oxygen cannot get into the body.

VIP binds specifically to alveolar type II cells (ATII) in lung alveolus, where it elicits anti-inflammatory/anti-cytokine activity in respiratory distress, acute lung injury, and inflammation. Aviptadil stimulates ATII cells to make more surfactant that must coat the lining of the lungs in order for them to exchange oxygen with the blood; loss of surfactant causes respiratory failure and alveolar collapse.

ARDS results from lung injury. The exact nature of the injury is not always clear. Common injuries are:

- Sepsis, a life-threatening condition occurs when your immune system must work aggressively to fight off infection or trauma
- Pneumonia (viral, bacterial, covid-19, Tuberculosis etc.)
- Inhaling harmful substances

- Trauma to the head, chest or other areas of the body
- Blood transfusions, injury to Pancreas, Near drowning

In the early stages of ARDS, fluid from the smallest blood vessels in the lungs starts to leak into the alveoli—the tiny air sacs where oxygen exchange takes place. The lungs become smaller and stiffer and it becomes hard to breath. The amount of oxygen in the blood falls. This is called hypoxemia. The body becomes starved for oxygen. This harms the brain and other tissues and leads to organ failure.

Patients with ARDS are short of breath, often to a distressing level. They are breathing faster and their heart is beating faster. They may have pain as they try to take a breath. As the oxygen in the blood falls, their fingernails and lips may have a bluish colour.

## **2. What you need to know before you take Oxyptadil®**

**Do not take Oxyptadil®** if you are allergic to hypersensitive to Aviptadil.

### **Warnings and precautions**

Consult with your doctor before taking Oxyptadil® if you have or have had cardiovascular or cerebrovascular conditions.

If you develop diarrhoea or loose stools during or after treatment, tell your doctor. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Driving and using machines**

Most people who get ARDS are already at the hospital for infection or trauma.

## **3. How to administer Oxyptadil®**

Your doctor will administer this medicine by an infusion pump in escalating doses for 3 successive days. One vial on Day 1, two vials on Day 2, and three vials on Day 3. The duration of the infusion depends on your body weight. Usually, infusion is administered in 12 hours.

## **4. Possible side effects**

Mild transient flushing of the face or trunk occurs commonly with Aviptadil infusion. Diarrhoea, hypotension, cutaneous flushing, facial flushing and infusion-related reactions may occur with Aviptadil treatment. Some side effects can be serious and need immediate medical attention.

Stop the Aviptadil on worsening the symptoms. If you develop these symptoms and your doctor give medical attention immediately.

### **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:

Website: [www.zuventus.co.in](http://www.zuventus.co.in) and click the tab “Safety Reporting” located on the top of the home page.

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

You can also report the side effect with the help of your treating physician.

### **5. How to store Oxyptadil®**

Do not take or give this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

This medicine requires to maintain at 2-8°C storage conditions. In case any foreign particulate is seen inside the vial do not use the vial for administration.

### **6. Contents of the pack and other information**

#### **What Oxyptadil® contains**

The active substance is Avipatdil (150 mcg in 10 mL).

#### **What Oxyptadil® looks like**

Oxyptadil® is an injection for Intravenous infusion and comes in a 10 mL vial size.

A vial of 10 ml.

#### **Marketing Authorisation Holder**

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**This leaflet was last revised in 07/2023.**