



**DRUG REGULATORY AUTHORITY OF PAKISTAN  
DIVISION OF PHARMACY SERVICES  
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS &  
COORDINATION  
ISLAMABAD**

**PHARMACOVIGILANCE ADVISORY NO. 02/2017-PS**

17<sup>th</sup> February 2017

**HYDROXYZINE HYDRO CHLORIDE**

Drug Regulatory Authority of Pakistan requires Package inserts/Prescribing information changes of Hydroxyzine hydrochloride to warn about potential risk of abnormal heart rhythm (QT prolongation or Torsade de pointes, ventricle tachycardia), restrict the use of hydroxyzine in patients at high risk of heart rhythm problems and using the medicine at the lowest effective dose for as short a time as possible.

Hydroxyzine hydrochloride a first generation antihistamine, prescribe in pruritus (itching), anxiety and as pre surgical medication in Pakistan.

**INFORMATION FOR HEALTH CARE PROFESSIONALS**

- Hydroxyzine has the potential to block hERG (potassium channels) and other types of cardiac channels, resulting in a potential risk of QT interval prolongation and cardiac arrhythmia events. This potential risk was confirmed by clinical and post-marketing data. Most cases had other risk factors, electrolyte abnormalities or concomitant treatment that may have been contributory.
- The maximum daily dose for adult is now reduced to 100mg/day for all indications and maximum daily dose in elderly if use cannot be avoided should not exceed 50mg.
- Use of hydroxyzine is contraindicated in patients with known acquired or congenital QT interval prolongation, or with a known risk factor for QT interval prolongation such as cardiovascular disease, significant electrolyte imbalance (hypokalemia, hypomagnesaemia), family history of sudden cardiac death, significant bradycardia, or concomitant use of



drugs known to prolong the QT interval and/or induce torsade de pointes (abnormal heart rhythm).

- Use is not recommended in elderly patients except if any other treatment option is not available, due to reduced elimination of Hydroxyzine in these patients and greater vulnerability to anticholinergic effects and other adverse reactions. The medicine should be used with caution in patients with bradycardia, or who are taking hypokalemia inducing medicines.

### **INFORMATION FOR PATIENTS**

- First generation antihistamine hydroxyzine hydrochloride is approved by the Drug Regulatory Authority of Pakistan for treatment of anxiety, relief of itching and as premedication before surgery.
- There is a small risk of altered electrical activity/conductivity of the heart when taking these medicines, which may lead to abnormal heart rhythm or even cause the heart to stop (cardiac arrest). This risk is mostly seen in patients who already have heart rhythm problems or have any risk factors for these problems.
- The drug, if use by adult the dose shall not exceed more than 100mg in a day in any conditions. Elderly patients should not use these medicines, but if they do the maximum dose shall not exceed 50mg a day.
- Hydroxyzine must not be taken by patients who already have disturbances of heart rhythm or are taking other medicines that can cause similar effects on the heart. It should be used with care if taking certain other medicines that slow the heart rate or decrease the level of potassium and magnesium in the blood.

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### **Further References:-**

- 1. European Medicines Agency (EMA).**
- 2. Medicines and Health Regulatory Authority (MHRA),United Kingdom.**
- 3. Pharmaceutical and Medical Devices Agency (PMDA),Japan.**
- 4. Health Canada.**