

1. What is Astemizole?

Astemizole is a medicine taken orally to relieve allergic symptoms. Astemizole belongs to a group of drugs called the non-sedating, second generation antihistamines. Second generation antihistamines differ from other antihistamines in that they may cause less drowsiness and less impairment of intellectual and motor functions.

2. Why are products containing Astemizole banned?

Use of astemizole with certain other drugs or foods and in certain medical conditions is associated with the potential to result in rare but serious side effects on heart primarily involving changes in heart rhythm. Some commonly prescribed antibiotics and anti-fungal medicines are known to increase blood levels of astemizole by affecting the way the body handles astemizole products. Other drugs and foods such as grapefruit juice may have a similar potential to alter blood levels of astemizole to a toxic level, thereby predisposing to rare and serious side effects on heart.

The list of drugs having the potential to interact adversely with astemizole is continuously growing. In addition, not all marketed drugs have been tested for the astemizole interaction.

3. What was done to address these safety concerns by DRA?

The DRA has notified the prescribers, pharmacy/medical shops and other dealers to stop importing and selling/dispensing products containing Astemizole.

4. How will I know if my products contain Astemizole?

Products containing this ingredient may be identified by looking for "Astemizole" in the list of active ingredients on the label. It is available as tablets, syrups.

If you are still unsure, check with the Pharmacy department, JDWNRH or contact DRA.

5. What are other medicines of the same category available in the market?

The other second generation antihistamines which are available in market to relieve allergy symptoms are cetirizine, loratadine.

6. How can I report a suspected side effect with any medicine?

You can report an adverse drug reaction at National Pharmacovigilance Centre, Pharmacy Department, JDWNR Hospital, Thimphu Bhutan, Tel: +975-2-322420 (ext 231)

[Email: pharmcentre@druknet.bt](mailto:pharmcentre@druknet.bt)

7. If I have questions about drug products whom can I contact?

Drug Regulatory Authority, Royal Government of Bhutan, P.O. Box No. 1556, Thimphu, Bhutan.

Telephone: 00975-2-337074/339015, Fax: 00975-2-335803, Drug Inspector: 337075/337076

Fax No: Fax: 00975-2-335803, Email: dra@druknet.bt, URL: <http://www.dra.gov.bt>