

1. What is Terfenadine?

Terfenadine is a medicine taken orally to relieve allergic symptoms such as runny nose, sneezing, itching of the nose or throat, and itchy watery eyes. Terfenadine 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 Terfenadine banned?

Use of terfenadine product with certain other drugs or foods and in certain medical conditions is associated with the potential to result in rare and serious cardiac side effects primarily involving changes in heart rhythm. Some commonly prescribed antibiotics and anti-fungal medicines are known to increase blood levels of terfenadine by affecting the way the body handles terfenadine-containing drugs. Other drugs and foods such as grapefruit juice may have a similar potential to alter blood levels of terfenadine 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 terfenadine-containing drugs is continuously growing. In addition, not all marketed drugs have been tested for the terfenadine interaction. Therefore, DRA recommends that consumers no longer use such product based on the risks/benefit profile of using terfenadine.

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

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

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

Drug products containing this ingredient may be identified by looking for “Terfenadine“in the list of active ingredients on the label. If you are still unsure, check with the Pharmacy department, JDWNRH or contact DRA.

6. What are other medicines of the same category available in the market? Other similar products in the market are fexofenadine (it superseded terfenadine), loratadine, cetirizine.

7. How can I report a suspected side effect with Terfenadine?

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)

8. 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>