

### **1. What is Rofecoxib?**

Rofecoxib is a pain medication used to relieve signs and symptoms of arthritis, acute pain in adults, and painful menstrual cycles.

### **2. Why are products containing Rofecoxib banned?**

The trial study showed that Rofecoxib may cause an increased risk in cardiovascular events such as heart attack and strokes especially when used for long duration. In the study trial, Rofecoxib was compared to placebo (sugar-pill). Therefore, DRA believes that the risks of using Rofecoxib outweigh the benefits and recommend that consumers no longer use such products.

### **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 Rofecoxib.

### **4. How will I know if my products contain Rofecoxib?**

Drug products containing this ingredient may be identified by looking for "Rofecoxib" 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 products of same category available in the market?**

Other similar products in the market are celecoxib which is still in use for specific treatment.

### **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)

### **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](mailto:dra@druknet.bt), URL: <http://www.dra.gov.bt>