

### **1. What is Nimesulide?**

Nimesulide is a pain medication belonging to group called Non Steroidal Anitnflammatory Drugs. It is indicated in the treatment of acute pain, symptomatic treatment of osteoarthritis (disease of bone and cartilage) and pain due to menstrual cycle in adolescents and adults above 12 years old.

**2. Why is Nimesulide and products containing Nimesulide banned?** Nimesulide inducing liver injury and hepatotoxicity have been reported fatal. Neonatal renal failure following the use of nimesulide has been reported. DRA believes that the risks of using nimesulide outweigh the benefits and recommends that consumers no longer use products containing nimesulide. There are safer pain medications of same category.

**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 Nimesulide.

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

Drug products containing this ingredient may be identified by looking for "nimesulide" in the list of active ingredients on the label. It is available as tablets, powder for dissolution in water, and topical gel.

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?** The other Non Steroidal Anti-inflammatory Drugs are diclofenac, aspirin, ibuprofen, naproxen.

**7. How can I report a suspected side effect with any other 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: 00975-2-335803, Email: [dra@druknet.bt](mailto:dra@druknet.bt), URL: <http://www.dra.gov.bt>