

F.No.12-01/12-DC Pt-05
Directorate General of Health Services
(Office of DCG (I))

FDA Bhawan
Kotla Road, New Delhi

Dated:

To

All State Drug Controllers

9th APR 2012

Sub: "Box Warning" on label as well as package insert and other promotional literature of formulations containing Nimesulide- regarding.

Sir,


It may be stated that the manufacture, sale and distribution of Nimesulide formulations for human use in children below 12 years of age was prohibited under Section 26A of Drugs and Cosmetics Act, 1940 vide Gazette Notification no. GSR 82(E) dated 10.02.2011.

The DTAB in its 60th meeting held on 10.10.2011 considered the use of Nimesulide in population of 12 years and above and after deliberations recommended that the following "Box Warning" should be mentioned on label as well as package insert and other promotional literature of formulations containing Nimesulide:

"Use of Nimesulide should ordinarily be restricted to 10 days. If longer clinical use is warranted, liver function test should be assessed periodically".

In view of above, you are requested to direct manufacturers of Nimesulide containing formulations for use in patients of 12 years and above in your state to incorporate above said box warning in a conspicuous manner on label, carton, package insert and other promotional literature of the drug.

Yours faithfully,


(Dr. G. N. Singh)
Drugs Controller General (India)

Copy to

All DDC(I)s/ADC(I)s of Zonal and sub-zonal offices of CDSCO