

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

FDA Bhawan  
Kotla Road, New Delhi

कार्यालय  
जीएचएस (एन.) नए दिल्ली  
25 APR 2012  
1302

Dated:

9 APR 2012

To  
All State Drug Controllers

Shri Dhad  
ADC

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.

DC

The DTAB in its 60<sup>th</sup> 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:

Circular  
to

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

all

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.

Put up on website too.

Yours faithfully,

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

Pl. act as per  
above Copy to  
instructions

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

27/4/2012

DA(D-2)

राजस्थान सरकार

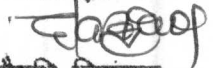
औषधि नियंत्रण संगठन, स्वास्थ्य भवन, तिलक मार्ग, जयपुर राज0

क्रमांक-डीसी/डी-2/अमेण्ड-2/2012/105

दिनांक 30.04.2012

प्रतिलिपि निम्न को सूचनाार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित है (on back Page)

- 1- समस्त सहायक औषधि नियंत्रक, राज0/समस्त औषधि नियंत्रण अधिकारी, राज0.
- 2- अध्यक्ष, राजस्थान फार्मास्यूटिकल्स मैनुफेक्चरर एसोसियेशन, जयपुर ।
- 3- इन्चार्ज, सर्वर रूम को भेजकर लेख है कि आप उक्त पत्र को विभागीय वेबसाईट पर डालने का कष्ट करें।

  
औषधि नियंत्रक  
राज0 जयपुर