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File No.4-01/2013-DC (Misc. 05)
Directorate General of Health Services
Office of Drugs Controller General (India)
(FDC Division)

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FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 14 FEB 2014

To,
All States/UTs Drugs Controller

Subject: **Restriction on use of formulations of Tramadol, Tapentadol as well as FDCs containing Tramadol-Regarding.**

Sir,

Formulaiton of Tramadol has been approved by this Directorate on 27.01.1993 for the purpose of severe acute and chronic pain, diagnostic measures and surgical pain. Further, formaulaiton of Tapentadol has been approved by this Directorate on 18.04.2011 for relief of moderate to severe acute pain in adults 18 years of age or older.

NDAC (Analgesics, Anesthetics & Rheumatology) in its meeting held on 22.03.2013 deliberated that Tramadol as well as Tapentadol has high potential for respiratory depressions and addiction. The committee recommended that all preparations of Tramadol as well as Tapendadol should be used for severe acute pain only for a period not exceeding 5 days.

You are therefore, requested to direct all the manufacturers manufacturing the preparation containing Tramadol or Tapentadol under your jurisdiction to comply with the aforesaid indication. The labels, package insert and other promotional literature of such products should be revised as above and submitted to this Directorate for further necessary aciton.

Action taken in this regard may be communicated by the manufacturers to this office in due course of time.

Yours faithfully,

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

Copy to:-
All Zonal/Sub Zonal offices of CDSCO.