

Prohibition of manufacturing sale & distribution of [Gatifloxacin](#) formulation for systemic use in human by any route including oral and inject able & [Tegaserod](#) & its formulations for human use regarding.

The Government of India, Ministry of Health & Family Welfare, in exercise of powers conferred under section 26A of the drugs & Cosmetic Act, 1940 has issued a Gazette Notification GSR 218(E) dated 16th March, 2011 prohibiting the manufacturing, sale & distribution of the use of these drugs was likely to involve certain risk to human beings where as safer alternatives of these drugs are available.

1. Gatifloxacin formulation for systemic sue in human by any route including oral & inject table &
2. Tegaserod & its formulations for human use.

Clarification

In view above it is clarified that Gatifloxacin ophthalmic formulation like eye drops & ointments which are topical formulations & are not for systemic use, are not covered under the Gazette notification no. GSR 218(E) dated 16/03/2011.



भारत का राजपत्र

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असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)प्राधिकार से प्रकाशित
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No. 139]नई दिल्ली, बुधवार, मार्च 16, 2011/फाल्गुन 25, 1932
NEW DELHI, WEDNESDAY, MARCH 16, 2011/PHALGUNA 25, 1932

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 16 मार्च, 2011

सां.का.नि. 218(अ).—जबकि केन्द्रीय सरकार इस बात से संतुष्ट है कि निम्नलिखित औषधों से मानव के लिए कुछ खतरे होने की सम्भावना है और जबकि उपर्युक्त औषधों के लिए अधिक सुरक्षित विकल्प उपलब्ध हैं;

और जबकि केन्द्र सरकार इस बात से संतुष्ट है कि यह उक्त औषधों के विनिर्माण, बिक्री और संचितरण पर जनहित में प्रतिबंध लगाना आवश्यक और समीचीन है;

अतः अब, औषध और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26-क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, केन्द्र सरकार एतद्वारा तत्काल प्रभाव से निम्नलिखित औषधों के विनिर्माण, बिक्री और संचितरण पर प्रतिबंध लगाती है, नामतः :—

- (i) मुख और इंजेक्शन सहित किसी भी मार्ग से मानव में क्रमबद्ध उपयोग हेतु गैटिफ्लोक्सासिन फार्मूलेशन; और
- (ii) मानव के इस्तेमाल के लिए टीगेसेरोड एवं इसके फार्मूलेशन।

[फा. सं. एक्स. 11014/1/2011-डी एफ व्जु सी]

डॉ. अरुण कुमार पण्डा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th March, 2011

G.S.R. 218(E).—Whereas the Central Government is satisfied that use of the following drugs is likely to involve certain risks to human beings and whereas safer alternatives to the said drugs are available;

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the manufacture, sale and distribution of the said drugs in public interest;

Now, therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture, sale and distribution of the following drugs with immediate effect, namely :—

- (i) Gatifloxacin formulation for systemic use in human by any route including oral and injectable; and
- (ii) Tegaserod and its formulations for human use.

[F.No. X. 11014/1/2011-DFQC]

Dr. ARUN KUMAR PANDA, Jt. Secy.

F.No. 12-01/11-DC (Pt. 27)
Office of Drugs Controller General (India)
Directorate General of Health Services
(New Drugs Division)

FDA Bhawan,
Kotla Road, New Delhi
Dated: **03 JUN 2011**

To

1. All State Drug Controllers
2. Indian Drug Manufacturer's Association (IDMA)
3. Organisation of Pharmaceutical Producers of India (OPPI)
4. Indian Pharmaceutical Alliance (IPA)

Subject: Clarification regarding continued availability of Gatifloxacin ophthalmic formulations – regarding.

Sir,

"Gatifloxacin formulation for systemic use in human by any route including oral and injectable" was prohibited for manufacture, sale and distribution in the country vide Gazette notification no. GSR 218(E) dated 16.03.11 issued by Ministry of Health & Family Welfare, Govt. of India.

This Directorate has received representations from State Drug Control Authorities, IDMA and other stake holders regarding clarification whether topical formulations (eye drops and eye ointments) of Gatifloxacin are covered under the said Gazette notification or not.

In view above it is clarified that Gatifloxacin ophthalmic formulations like eye drops and ointments which are topical formulations and are not for systemic use, are not covered under the Gazette notification no. GSR 218(E) dated 16.03.11

Above clarification is being issued with concurrence of the Ministry of Health & Family Welfare.

Yours faithfully,



Dr. Surinder Singh
Drugs Controller General (India)

Copy for information to: All Zonal & Sub-Zonal offices of CDSCO.