

THE GAZETTE OF INDIA: EXTRAORDINARY [PART II—SEC. 3(ii)]

**MINISTRY OF HEALTH AND FAMILY WELFARE**

**(Department of Health and Family Welfare)**

**NOTIFICATION**

New Delhi, the 8th June, 2017.

**S.O. 1851(E).**—whereas it had been brought to the notice of the Central Government that the use of the drug **fixed dose combination of Nimesulide + Levocetirizine** is not rational; And, whereas, the matter has been examined by the Subject Expert Committee constituted by the Central Government and the said Committee has recommended to the Central Government that the said fixed dose combination does not have therapeutic justification and the drug could be its misused and overuse incases where a single drug is required;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for human use of the said drug in the country;

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 for sale, sale and distribution for human use of the drug **fixed dose combination of Nimesulide + Levocetirizine** with immediate effect.

[F. No. X.11014/12/2017-DRS]

K. L. SHARMA, Jt. Secy.

**S.O. 1852(E).**—whereas it had been brought to the notice of the Central Government that the use of the drug **fixed dose combination of Ofloxacin + Ornidazole injection** is not rational; <sup>1</sup> And, whereas, the matter has been examined by the New Drugs Advisory Committee constituted by the Central Government and the said Committee has recommended to the Central Government that the said fixed dose combination is not rational and there is no specific advantage an administering both drugs together in parental form and as such there is no therapeutic justification for the continued marketing of this drug;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for human use of the said drug in the country;

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 for sale, sale and distribution for human use of the drug **fixed dose combination of Ofloxacin + Ornidazole injection** with immediate effect.

[F. No. X.11014/12/2017-DRS]

K. L. SHARMA, Jt. Secy.

**S.O. 1853(E).**—Whereas it had been brought to the notice of the Central Government that the use of the drug **fixed dose combination of Gemifloxacin + Ambroxol** is not rational and is likely involve risk to human beings; And, whereas, the matter has been examined by Subject Expert Committee constituted by the Central Government and the said Committee recommended to the Central Government that the said drug does not have sufficient therapeutic justification as the drug Ambroxol does not have any added advantage in antimicrobial activity;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for human use of the said drug in the country;

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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 for sale, sale and distribution for human use of the drug **fixed dose combination of Gemifloxacin + Ambroxol** with immediate effect.

[F. No. X.11014/12/2017-DRS]

K. L. SHARMA, Jt. Secy.

**S.O. 1854(E).**—Whereas it had been brought to the notice of the Central Government that the use of the drug **fixed dose combination of Glucosamine + Ibuprofen** is not rational; And, whereas, the matter has been examined by the Subject Expert Committee constituted by the Central Government and the said Committee recommended to the Central Government that the said drug lacks rationality and therapeutic justification;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for human use of the said drug in the country;

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 for sale, sale and distribution for human use of the drug **fixed dose combination of Glucosamine + Ibuprofen** with immediate effect.

[F. No. X.11014/12/2017-DRS]

K. L. SHARMA, Jt Secy.

**S.O. 1855(E).**—Whereas it had been brought to the notice of the Central Government that the use of the drug **fixed dose combination of Etodolac + Paracetamol** is not rational;

And, whereas, the matter has been examined by the New Drugs Advisory Committee constituted by the Central Government and the said Committee has recommended to the Central Government that the said fixed dose combination drug does not have therapeutic justification and the two drugs are best administered separately on as required basis;

And, whereas, after examination of the recommendations of the aforesaid Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition, the manufacture for sale, sale and distribution for human use of the said drug in the country;

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 for sale, sale and distribution for human use of the drug **fixed dose combination of Etodolac + Paracetamol** with immediate effect.

[F. No. X.11014/12/2017-DRS]  
K. L. SHARMA, Jt. Secy.