



GOVERNMENT OF JAMMU & KASHMIR
OFFICE OF THE PRINCIPAL GOVERNMENT MEDICAL COLLEGE SRINAGAR
10-Karan-Nagar, Srinagar, Kashmir, 190010. Phone No.0194-2504114,
FAX : 0194-2503115



All Head of Departments/ HOU's/
_____ GMC, Srinagar.

No: PS/MC/18/1526-30

Dated:- 07-11-2018


Subject: Safety issues with Fluoroquinolone Antibiotics- Action taken by
USFDA.

Sir/Madam,

Drugs Controller General (India) as a part of ongoing Pharmacovigilance Programme of India (copy attached) communicated the safety issues of Fluoroquinolone Antibiotics that are commonly used to treat a variety of illnesses such as respiratory and urinary tract infections can cause low blood sugar and mental health related side effects.

In light of the safety issues reported by USFDA, Pharmacovigilance Programme of India have circulated communication (copy attached) for monitoring of any such adverse event in your department/unit, you are requested to communicate the same to Adverse Drug Reaction Monitoring Centre, Department of Pharmacology, Government Medical College Srinagar, for taking further appropriate necessary action.

Encl:


(Prof. Samia Rashid)
Principal & Dean
Govt. Medical College Srinagar

CC:

1. Head of Department Pharmacology, GMC Srinagar for information and n/action
2. Registrar Academics, GMC Srinagar for information
3. Medical Superintendents of Associated Hospitals for information and n/action
4. I/C IT section for uploading the letter on official website
5. Office record file

F.No.12-01/18-DC(Pt-230)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi – 110002 (India)
New Drugs Division

Dated: 23-10-2018

To
All State/UT Drug Controllers

Subject:- Safety Issues with Fluoroquinolone Antibiotics – Action taken by USFDA regarding

Sir/Madam

Fluoroquinolones are antibiotics that are commonly used to treat a variety of illnesses such as respiratory and urinary tract infections. These medicines include ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin, norfloxacin, ofloxacin, etc.

USFDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects.

In light of the safety issues reported by USFDA, the matter was examined by CDSCO in consultation with the Subject Expert Committee (SEC) (Antimicrobial & Antiviral) in its meeting held on 07.08.2018

The committee deliberated the matter in detail and recommended that the manufacturers of Fluoroquinolone antibiotics should mention various cautions in the Label/Package insert/Promotional literature of the drugs.

Accordingly, you are requested to direct the manufacturers of fluoroquinolones under your jurisdiction to mention following cautions in the label/Package insert/Promotional Literature of the drugs.

1. The label of the product should mention following caution :-

This drug may cause low blood sugar and mental health related side effects.

2. Package insert and promotional literature should mention the details as follows :-

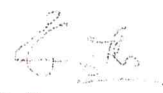
"The drug may cause low blood sugar and mental health related side effects. Low blood sugar levels, also called hypoglycaemia, can lead to coma. The mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are:

- disturbances in attention
- disorientation

- agitation
- nervousness
- memory impairment
- Serious disturbances in mental abilities called delirium."

Action taken in the matter may please be intimated to this office at the earliest.

Yours faithfully



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy for necessary follow up to:

All Zonal/Sub Zonal offices of CDSCO

Copy for information to:-

JS(R), Nirman Bhawan , MoHFW, Delhi-110002.