

F. No. 12-01/18-DC (Pt-337)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated: **19 JUN 2019**

To,

All State/UT Drugs Controllers,

Sub: Artemether+Lumefantrine – Steven Johnson Syndrome (SJS) - Reg.

Sir,

Artemether+Lumefantrine is approved by CDSCO and marketed in the country.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Artemether+Lumefantrine which were discussed by them in the 12th Signal Review Panel (SRP) under the programme meeting held on 27.03.2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Artemether+Lumefantrine - ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate Steven Johnson Syndrome (SJS) in to the prescribing information leaflet (PIL) of the drug Artemether+Lumefantrine marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 13.06.2019 at CDSCO HQ, New Delhi. After detailed deliberation the Committee has recommended that Steven Johnson Syndrome (SJS) should be incorporated as an adverse drug reaction in the package insert of the drug Artemether+Lumefantrine as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Artemether+Lumefantrine formulations under your jurisdiction to mention Steven Johnson Syndrome (SJS) as an adverse drug reaction in the Package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,



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

1. Copy for information & follow-up: -
All Zonal / Sub Zonal Offices of CDSCO.

2. Copy for information to: -
JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.