

File No.: 04-01/2022-DC (Misc.-47)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

18 DEC 2023

To,
All State/UTs Drugs Controllers,

Subject: To update package insert/Promotional Literature of FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml - regarding.

Sir,

The FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml was declared as rational by Prof. Kokate committee and based on the recommendation of the committee, this office has issued NOC for continued manufacturing and marketing of subject FDC on 17.07.2015 under the 18 months policy decision.

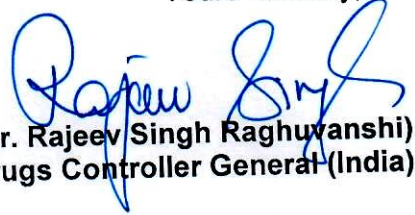
Subsequently concerns have been raised regarding promotion of unapproved anti-cold drug formulation for infants. The matter was deliberated in Subject Expert Committee (SEC- Pulmonary) meeting held on 06.06.2023 wherein, In light of the issue regarding use of the FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCL IP 5mg drop/ml was discussed before the committee. The committee recommended that the FDC should not be used in children below 4 years of age and accordingly the firms should mention warning in this regard on label and package insert.

The recommendation of the SEC has been considered by this office.

Accordingly, you are requested to direct all the manufacturers of said FDC under your jurisdiction to mention warning "**FDC should not be used in children below 4 years of age**" on label and package insert/Promotional Literature of the drug.

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

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:-

1. All Zonal/Sub Zonal offices of CDSCO
2. Indian Drug/Pharmaceuticals Association Forum
3. Website of CDSCO