

Government Restricts Manufacture, Sale and Distribution of Fixed Dose Combinations Containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride for Use in Children Below Four Years

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In a significant step to safeguard the health and safety of young children, the Government has imposed restrictions on the manufacture, sale and distribution of all Fixed Dose Combinations (FDCs) containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride, mandating a clear warning that these medicines shall not be used in children below four years of age.

Earlier, vide notification dated 15 April 2025 [S.O. 1717(E)], the Government had restricted certain FDCs containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride, subject to the same age-specific warning. The latest notification extends this requirement to all formulations containing these two ingredients.

The decision has been taken following the recommendations of an Expert Committee and the Drugs Technical Advisory Board (DTAB). The Government noted that the use of such combinations may pose risks to children below four years of age and that safer alternatives are available.

Manufacturers have been directed to clearly display the warning, "Fixed Dose Combination shall not be used in children below four years of age," on the label, package insert and promotional literature associated with these formulations.

The notification has been issued under Section 26A of the Drugs and Cosmetics Act, 1940, in the interest of public health and is effective from the date of its publication in the Official Gazette.

The Official Gazette can be accessed through this: <https://egazette.gov.in/WriteReadData/2026/275640.pdf>

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