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Government bans FDCs containing chlorpheniramine malate and phenylephrine hydrochloride for children below 4

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Notification has been issued in the interest of public health under Section 26A of the Drugs and Cosmetics Act, 1940



In an important step to protect the health and safety of young children, the government has banned the manufacture, sale, and distribution of all fixed dose combinations (FDCs) containing chlorpheniramine malate and phenylephrine hydrochloride, and mandated that these drugs should not be used in children below the age of four.

Earlier, through the Notification [SO 1717(E)] dated 15th April 2025, the government had banned certain Fixed Dose Combinations (FDCs) containing Chlorpheniramine Malate and Phenylephrine Hydrochloride, imposing age-specific warnings. The latest notification imposes this requirement on all formulations containing these two ingredients.

The decision has been taken following the recommendations of the Expert Committee and the Drugs Technical Advisory Board (DTAB). The government said that the use of such a combination could pose a risk to children under the age of four and that safer alternatives are available.

Manufacturers have been directed to clearly display on the labels, package inserts and promotional material related to these drugs with a clear warning, "Fixed dose combinations should not be used in children below four years of age." "

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