August 18, 2026

CDSCO

All chlorpheniramine-phenyl FDCs need an under-4 warning

S.O. 4595(E) of August 18, 2026 requires a warning against use in children below four on every FDC with chlorpheniramine maleate and phenylephrine hydrochloride.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification S.O. 4595(E), dated August 18, 2026, under section 26A of the Drugs and Cosmetics Act, 1940. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 4415, dated August 19, 2026; the e-Gazette copy was digitally signed on August 21, 2026. It is signed by Harsh Mangla, Jt. Secy., under F. No. X.11035/132/2024-DR, the same file number as S.O. 1717(E) of April 15, 2025.

KEY FACTS

AUTHORITY

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Ministry of Health and Family Welfare (Department of Health and Family Welfare)

DOCUMENT

Notification S.O. 4595(E), under section 26A of the Drugs and Cosmetics Act, 1940

All chlorpheniramine-phenylephrine FDCs need an under-4 warning

CDSCO · August 18, 2026

The Ministry of Health and Family Welfare (Department of Health and Family Welfare) issued notification S.O. 4595(E), dated August 18, 2026, under section 26A of the Drugs and Cosmetics Act, 1940. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 4415, dated August 19, 2026; the e-Gazette copy was digitally signed on August 21, 2026. It is signed by Harsh Mangla, Jt. Secy., under F. No. X.11035/132/2024-DR, the same file number as S.O. 1717(E) of April 15, 2025.

S.O. 1717(E) restricted the manufacture, sale or distribution of all formulations of the fixed dose combination (FDC) of Chlorpheniramine Maleate + Phenylephrine Hydrochloride, on condition that manufacturers mention a warning against use in children below four years of age. The new notification records that the Central Government is satisfied that the use of other drug FDCs containing the two drugs is likely to involve risk to children below four years of age. It also records that safer alternatives to such drugs are available. An Expert Committee constituted by the Ministry examined those FDCs and recommended that the same warning apply to all formulations of FDCs containing both drugs "manufactured or imported and marketed in India".

At its meeting held on February 16, 2026, the Drugs Technical Advisory Board examined the proposal to restrict the manufacture for sale or for distribution of all formulations of FDCs containing both drugs, in addition to S.O. 1717(E). After detailed deliberation, it agreed that such formulations shall not be used in children below four years of age. On that basis, the Central Government restricts the manufacture, sale or distribution of all formulations of FDCs containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride. The condition is that their manufacturers mention the warning "fixed dose combination shall not be used in children below four years of age" on the label and package insert or the promotional literature of the drug. The notification comes into force on the date of its publication in the Official Gazette.

The notification lists no products, strengths or brands, and does not name the other drugs a covered FDC may contain. Its operative paragraph speaks of manufacture, sale or distribution and does not mention import; the words "manufactured or imported and marketed in India" appear only in the recital on the Expert Committee's recommendation. It gives no transition period for stock already made or on the market, and does not say whether labels or inserts already printed may still be used. CDSCO's list of Gazette notifications titles it a "Prohibition" of these FDCs "in children below four years of age"; the notification's own word is "restricts".

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification S.O. 4595(E), under section 26A of the Drugs and Cosmetics Act, 1940

Dated	August 18, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), No. 4415, August 19, 2026
Applies to	All formulations of fixed dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride; the condition is on their manufacturers
Takes effect	On publication in the Official Gazette; the Gazette issue is dated August 19, 2026
Warning	"fixed dose combination shall not be used in children below four years of age"
Where it must appear	On the label and package insert or the promotional literature of the drug
Earlier notification	S.O. 1717(E), April 15, 2025: the same warning on all formulations of the FDC of Chlorpheniramine Maleate + Phenylephrine Hydrochloride
Based on	An Expert Committee of the Ministry; the Drugs Technical Advisory Board meeting of February 16, 2026
Transition period	Not stated
File number	F. No. X.11035/132/2024-DR
Signed by	Harsh Mangla, Jt. Secy.

The notification (PDF, 660 KB)

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