

# India bans select cough syrups for children under 4 amid safety concerns

The Indian government has prohibited the use of certain cough syrups containing chlorpheniramine maleate and phenylephrine hydrochloride in children below four years, citing safety issues.

## In Short

- Govt restricts FDC cough syrups for kids under 4
- Popular brands like Ascoril, T-Minic affected
- Delhi HC exempts pre-April 15 stock from ban

On April 15, 2025, the government of India released an order restricting the manufacture, distribution, and sale of fixed-dose combination (FDC) cough syrups for children under the age of four that contain chlorpheniramine maleate and phenylephrine hydrochloride. This came after the recommendation from DTAB and the Subject Expert Committee, which emphasised the issues relating to the safety and effectiveness of these products in young children.

The previously mentioned medicines include popular brands such as Ascoril Flu Drops and some of Alex by Glenmark, T-Minic by Haleon (previously GlaxoSmithKline), and Maxtra by Zuentus Healthcare. These manufacturers are now required to add label and package insert warnings that say: "Combination of FDC shall not be given to children below four years of age."

Glenmark and Zuentus Healthcare contested the government's notification claiming that it was illegal to apply it retrospectively. On April 24, 2025, the ruling of the Delhi High Court delegated that this ban will be implemented as sequential meaning it will not include stocks that were made before April fifteen as they were exempted.

Nonetheless, the court required these companies to inform all medical professionals through formal advisories and public notices in widely circulated newspapers stating that these FDC cough syrups must never be given to children under four years regardless of the situation.

Additionally, the manufacturers were ordered by the court to submit sworn statements regarding the produced and distributed stocks prior to the new guidelines coming into effect so as to maintain compliance and transparency.

Pharmacists around the nation have raised issues pertaining to the management of remaining stock of the banned cough syrups post the ban. The IPA or the Indian Pharmaceutical Association has consulted the DCGI or the Drugs Controller General of India inquiring whether the remaining supply is meant to be returned or can be sold until there is zero stock left. Moreover, there is a need for clarification on the dispensing of prescriptions meant for toddlers during this period of shifting policies.

The stakeholders include the manufacturers, pharmacists, and health care service providers, along with other stakeholders. As such, they have also been suggested alongside more time in the adaptation period to ensure the new regulations are seamlessly integrated.

The measures imposed by the government highlight the necessity of safeguarding children's medicines. The restrictions placed on using selected FDC cough syrups in very young children are intended to avoid certain negative outcomes and safeguard the interests of this sensitive age group.

The public notices, along with the warnings, are directed towards ensuring that as a professional, one pays more attention to the targeted health care services and therapeutics as they relate to caregiving.

As monitoring changes within the processes of these healthcare sectors, it is crucial that the guardians, pharmaceutical practitioners, and the rest involved in the regulation work closely together to protect the young children's wellbeing while being fully responsible for adapting to the new instruction policies.

## News Source:

<https://www.indiatoday.in/information/story/india-bans-select-cough-syrups-for-children-under-4-amid-safety-concerns-2714917-2025-04-25>