Generic Name:
Multiple generic names
Trade Name:
Multiple trade names
Company:
Multiple companies
Notes:

FDA is requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit use of these products to adults 18 years and older. FDA has determined the risks of these medicines outweigh their benefits in children younger than 18.

Health professionals should reassure parents that cough resulting from a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include OTC products such as dextromethorphan, as well as prescription benzonatate products.

FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the boxed warning, the most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

Some codeine cough medicines are available OTC in a few states, and FDA is also considering regulatory action for these products.

FDA is taking this action after conducting an extensive review and convening a panel of outside experts. Both of these determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

See the FDA Drug Safety Communication for a list of prescription cough and cold medicines containing codeine or hydrocodone.

Medication Monitor Categories:
Alerts and Recalls