Codeine black box warning

Codeine has been prescribed to pediatric patients for many decades as both an analgesic and an antitussive agent. Codeine is a prodrug with little inherent analgesic effect. Codeine is an opiate used to treat pain, as a cough medicine, and for diarrhea. It is typically used to treat mild to moderate degrees of pain. Greater benefit may. On February 20, 2013, the U.S. Food and Drug Administration (FDA) issued a public warning to address a safety concern with the use of codeine in TEENren after. warning: the combination of promethazine hydrochloride and codeine phosphate is contraindicated in pediatric patients less than 16 years of age. Black box warnings (BBWs) are the strongest medication-related safety warnings in a drug's labeling information and highlight major risks. Absence of a BBW or. Note: Press announcements from 2004 to 2014 are available through the FDA.gov Archive. Some links in press announcements may no longer be active.