

# Texas Vendor Drug Program

## Drug Use Criteria: Promethazine Use in Children Less Than 2 Years of Age

### Publication History

- Revised Sept. 2019; Sept. 2017; Aug. 2015; Dec. 2013; Feb. 2012; May 2010. Developed Oct. 2006

### Notes

- Information on indications for use or diagnosis is assumed to be unavailable. All criteria may be applied retrospectively; prospective application is indicated with an asterisk [\*]. The information contained is for the convenience of the public. The Texas Health and Human Services Commission is not responsible for any errors in transmission or any errors or omissions in the document.
- Medications listed in the tables included in these retrospective criteria are not indicative of Vendor Drug Program formulary coverage.

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**TEXAS**  
Health and Human  
Services

*Medical and  
Social Services*

# 1 Dosage

## 1.1 Pediatrics

In 2004, promethazine received a “black box” warning with contraindications for use in children under two years of age and strengthened warnings for use in children two years of age and older. These revisions resulted from repeated reports to the Food and Drug Administration (FDA) of serious, life-threatening adverse events in children. Between 1969 and 2003, the FDA received 125 reports of adverse events in the pediatric population including respiratory depression, apnea, or cardiac arrest (n = 38); dystonic reactions (n = 29); unspecified central nervous system reactions (n = 24); seizures or seizure-like activity (n = 15); dermatologic reactions (n = 12); and neuroleptic malignant syndrome (n = 5). All routes of administration were responsible for the outcomes observed with these events, which included hospitalization, life-threatening events, disability, and death.<sup>1-6</sup>

Due to the limitations placed on promethazine prescribing, all profiles for patients under two years of age containing prescriptions for promethazine will be reviewed.

## 2 References

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3. Facts and Comparisons eAnswers [database online]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; 2019; Sept. 6, 2019.
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6. Promethazine hydrochloride syrup package insert. Hi-Tech Pharmacal Co., Inc., Sept. 2017.
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