

Safety Alert

March 2024

Benzyl alcohol containing products —Risk of gasping syndrome in young children & Allergic reaction and mild local irritation.

EDA performs label update to include the following:

Special warnings and precautions for use

All Types of application:

Benzyl alcohol can cause allergic reactions.

When used orally or parenterally:

- Benzyl alcohol has been associated with a risk of serious adverse reactions (gasping syndrome) in newborns and young children.
- In Young children (Under 3 years of age) the drug should not be used for longer than one week due to accumulation.
- Large amounts of benzyl alcohol should only be used with caution and when absolutely necessary because of the risk of accumulation and toxicity (metabolic acidosis) especially in people with impaired liver or kidney function and during pregnancy and breast -feeding.

When applied topically:

Benzyl alcohol can cause mild local irritation

Background:

The preservative benzyl alcohol may cause hypersensitivity reactions. Intravenous administration of benzyl alcohol has been associated with serious adverse events, and death in paediatric patients including neonates (“gasping syndrome”). Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the “gasping syndrome”, the minimum amount of benzyl alcohol at which toxicity may occur is not known.

Benzyl alcohol containing formulations should only be used in neonates if it is necessary and if there are no alternatives possible. Premature and low-birth weight neonates may be more likely to develop toxicity. Benzyl alcohol containing formulations should not be used for more than 1 week in children under 3 years of age unless necessary. It is important to consider the total quantity of benzyl alcohol received from all sources, and high volumes should be used with caution and only if necessary, especially in patients with liver or kidney impairment, as well as in pregnant or breast-feeding women, because of the risk of accumulation and toxicity (metabolic acidosis)

References:

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