

AAP News Parent Plus

INFORMATION FROM YOUR PEDIATRICIAN

Check ingredients before using prescription ear drops on children

Parents who have over-the-counter or prescription ear drop medication for their children should check the package label. One infant has died, and other infants and children have been harmed by medications that were not approved by the Food and Drug Administration (FDA) as safe and effective.

The FDA issued a safety warning about ear products that contain the following ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine and zinc acetate;
- benzocaine, chloroxylenol and hydrocortisone;
- chloroxylenol and pramoxine; or
- chloroxylenol, pramoxine and hydrocortisone.

Ear medications with these ingredients do not work as intended. They might be harmful to children because the quality and the amount of active ingredient they contain is not known.

One infant died when his caregiver used ear drops that had too much benzocaine. The overdose of benzocaine caused a blood disorder called methemoglobinemia. Other children have experienced allergic reactions and symptoms such as itching, stinging, burning and irritation of the ear.

Parents sometimes use ear drops when their child has symptoms of an ear infection, excess buildup of earwax or to prevent swimmer's ear. The American Academy of Pediatrics (AAP) advises parents to only use products that are labeled as FDA-approved. Safe prescription and over-the-counter drugs are available.

Parents should never put objects like cotton-tip swabs, pencils, fingers or paperclips into the ear canal, the AAP advises. Contact your pediatrician if you suspect your child's ear canal is blocked by wax. Your pediatrician also can determine whether your child has an ear infection and if antibiotics are needed.

If you think you are using unapproved prescription ear drops, contact your pediatrician for alternatives. Report any side effects at www.fda.gov/Safety/ReportaProblem/ucm059315 or by calling 800-332-1088.



— Trisha Koriath