

SFDA Safety Communication

[26/10/2025]

Potential Risk of Medication Errors with Paracetamol Use in Pediatrics

The Saudi Food and Drug Authority (SFDA) would like to remind the healthcare professionals and the public about the potential risk of medication errors, including overdose, wrong dose and improper administration technique, associated with the use of paracetamol in pediatrics. The usual recommended dose of paracetamol for pediatrics is 15-10 mg per kg.

The SFDA advises healthcare professionals to ensure:

- Verify product concentration before prescribing or dispensing paracetamol, as multiple concentrations (e.g., 100 mg/ml vs. 120 mg/5 ml and 160mg/ml suspensions) are available in the market.
- Always calculate the dose based on body weight (recommended 10–15 mg/kg per dose, not exceeding the maximum daily limit).
- Provide clear written instructions to caregivers, specifying both the dose in mg and the exact volume in milliliters (ml). Avoid using only “drops” as a measure.
- Ensure the availability and suitability of the measuring device calibrated in milliliters (mL) prior to dispensing. If the measuring device is missing, unsuitable, or calibrated in units other than mL, report the issue spontaneously to the SFDA and the Marketing Authorization Holder (MAH).

- Counsel parents/caregivers on the proper use of the dropper, emphasizing that the oral drops are highly concentrated and that overdosing can occur easily if misused.
- Double-check prescriptions when switching between different formulations of paracetamol (drops, suspension, or suppositories) to avoid accidental overdose.
- Encourage parents to use the SFDA paracetamol calculator for dose confirmation: [SFDA Calculator](#).

For Parents and Caregivers:

- Do not guess the dose. Always use the instructions given by your doctor or pharmacist.
- Use the measuring device provided with the medicine. Do not substitute with household spoons, as this can result in incorrect dosing.
- If the measuring device provided with the product is missing, not calibrated in milliliters (mL), unclear to read, or calibrated in units other than mL, causing confusion, please report the issue spontaneously to the SFDA and your healthcare provider.
- Check the concentration on the label carefully before giving the medicine. Paracetamol drops (100 mg/ml) are stronger than suspensions, so a much smaller amount is needed.

- Calculate the dose based on your child's weight and confirm with your healthcare provider.
- Never exceed the recommended daily dose.
- Keep the medicine out of children's reach to prevent accidental ingestion.
- If unsure about the dose or if your child vomits/spits the medicine, consult your doctor or pharmacist before repeating the dose.
- Visit the SFDA awareness page for more guidance: [SFDA Awareness Campaign](#).
- Use the SFDA paracetamol calculator for dose confirmation: [SFDA Calculator](#).

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

Website: <https://ade.sfda.gov.sa>

SFDA RMM Webpage:

