

Saudi Food & Drug Authority (SFDA)

SAFETY COMMUNICATION

28-11-2019

Concerns on paracetamol overdose in children.

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare professionals about important directions for paracetamol use in children to avoid the possibility of paracetamol overdose.

Healthcare professionals should consider the following:

- Paracetamol might be available as single component product or in combination with cough and cold medications. Therefore, parents should be instructed to carefully examine the active ingredients of products given to their child.
- Co-administration of other products containing paracetamol (e.g. cough and cold medications) might occur. Although these products are not generally recommended in young children. If they are used, instruct the parent that the paracetamol component must be included in calculations for the maximum total daily dose.
- Inform parents that the oral route is preferred over rectal use. However, if they are co-administered, the paracetamol component must be also included in calculations for the maximum total daily dose. Paracetamol liquid is available in several concentrations. Therefore, the dose from one product to another might be different. Instruct parents to read the package insert to identify the proper dose for their child.
- The use of spoons as measuring device might be confusing and may result in incorrect doses given to children. Parents should be counselled about the proper use of the measuring device (cup or syringe) that usually comes with the product. If the measuring device is not supplied with the product then parents should ask their pharmacist about administration instruction
- Ensure that the parent knows the dosing interval and the maximum number of doses per day
- Ensure that families with more than one child to be aware of the different doses required for each child and that there are different strengths of paracetamol liquid available.
- Advise parents to seek medical attention if fever does not abate in three days

Report Adverse Drug Events to the SFDA

The SFDA urges healthcare professionals to report adverse drug events to the SFDA using the following contact information:

National Pharmacovigilance Center (NPC)

Saudi Food and Drug Authority-Drug sector

4904Northern ring branch re-

Hitteen District

Riyadh 13513 - 7148

Kingdom of Saudi Arabia

Reporting hotline: 19999

Fax: +966112057662

Email: npc.drug@sfda.gov.sa

Webpage: <http://ade.sfda.gov.sa>