



## Direct Healthcare Professional Communication

June 2025

### **Paracetamol – Reminder of proper use and risks associated with overdose**

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to Remind you **about proper use and risks associated with overdose**

#### ***Summary***

- Paracetamol is widely used in Egypt and the hepatotoxicity is well known risk of Paracetamol acute poisoning, so PVGA wants to remind healthcare professionals about the potential risk of hepatotoxicity and the serious risks associated with overdose and the proper use of this medication.
- Paracetamol is a medication indicated for the symptomatic treatment of pain and fever. Although it is safe when used according to its marketing authorization, misuse can lead to serious health risks.
- The first symptoms (usually within 24 hours) of an overdose can include nausea, vomiting, abdominal pain, and profuse sweating. After three to four days, severe, irreversible liver damage, or even death in some cases, can occur. To avoid this, compliance with the dosage and precautions for use are essential.

#### ***Background on the safety concern***

The hepatotoxicity of paracetamol in cases of acute poisoning is well known. An overdose can also cause kidney and brain damage.

In adults, significant toxicities can be expected from a cumulative intake of 10 grams, in children from 150 mg/kg. In the presence of risk factors, toxicity can already be observed with lower doses, as well as in the case of chronic use of the usual maximum daily dose (4 grams). Any suspicion of overdose requires immediate medical attention.

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### ***Information for patients – advice to be given at the time of prescription and/or dispensing:***

- Read the medication instructions carefully and follow your doctor's prescription and/or the recommendations from his pharmacist.
- Discuss with them the dangers of misuse of medications which could lead to irreversible damage, in some cases.
- Keep medicines out of reach of children to avoid accidental ingestion or overdose.
- Avoid the simultaneous use of several medications containing paracetamol. Over 135 medications in EGYPT contain paracetamol alone or in combination with other active substances. One of the causes of accidental overdose is the simultaneous use of several products containing paracetamol.
- In case of overdose, contact your doctor or pharmacist immediately

### ***Reference***

#### **Luxem:**

<https://santesecu.public.lu/dam-assets/fr/espace-professionnel/domaines/dhpc/dhpc-2025/2025-paractamol.pdf>

### **Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://vigiflow-eforms.who-umc.org/eg/med>

QR Code:

PO Box: 11451

Hotline: 15301

