

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

אקמול טבע טבליות, אקמול טבע קפליות

Acamol Teva Tablets, Acamol Teva Caplets

Contains: Paracetamol 500mg

התוויה כפי שאושרה בתעודת הרישום:

- Relief of pain and fever of different etiologies such as headache, toothache, colds, influenza, rheumatic pain and dysmenorrhea.

עדכונים בעלון לרופא

בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע בטקסט מחוק):

*4.4 Special warnings and precautions for use*

[...]

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Do not exceed the stated dose.

Patients should be advised to consult their doctor if their headaches become persistent.

Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis (refer also to section 4.9).

~~Use with caution in patients with glutathione depletion due to metabolic deficiencies.~~

In the case of high fever, or signs of secondary infection or persistence of symptoms a doctor should be consulted. Immediate medical advice should be sought in the event of overdose even if the patient feels well because of the risk of irreversible liver damage (see section 4.9).

**If symptoms persist consult your doctor.**

**Keep out of the sight and reach of children.**

[...]

## **5.1 Pharmacodynamic properties**

[...]

### Mechanism of Action

Analgesic – the mechanism of analgesic action has been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain-impulse generation.

~~The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.~~

Antipyretic – paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

העלונים נשלחו למרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

וניתן לקבלו מודפס ע"י פניה לחברת טבע. <https://israeldrugs.health.gov.il>