

חברת טבע מודיעה על העדכונים הבאים בעלון לצרכן ולרופא של התכשיר

אקמול טבליות, אקמול קפליות

Acamol Tablets, Acamol 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 כטקסט מחוק):

4.4 Special warnings and precautions for use

[...]

~~Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol.~~

~~Close monitoring, including measurement of urinary 5-oxoproline, is recommended.~~

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of

glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Flucloxacillin: Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, due to pyroglutamic acidosis especially in patients with risks factors (see section 4.4)

4.8 Undesirable effects

Frequency	System	Symptoms
[...]		
<u>Not Known</u>	<u>Metabolism and nutrition disorders</u>	<u>High anion gap metabolic acidosis (HAGMA)</u>

[...]

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4).



Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

העלונים נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
<https://israeldrugs.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.