



יולי 2020

רוקח/ת נכבד/ה,
רופא/ה נכבד/ה,

**הנדון: עדכונים בעלון לרופא לתכשיר
Clopixol Acuphase 50 MG/ ML , Solution for Injection
קלופיקסול אקופז 50 מ"ג/ מ"ל, תמיסה להזרקה**

חברת לונדבק ישראל בע"מ מבקשת להודיע כי העלון לרופא לתכשיר קלופיקסול אקופז 50 מ"ג/ מ"ל, תמיסה להזרקה המכילה את החומר הפעיל Zuclopenthixol acetate בריכוז 50 מ"ג/ מ"ל עודכן ביולי 2020.
ההתוויה המאושרת לתכשיר:

Acute psychoses.

בהודעה זו מצוינים סעיפים בהם נעשה עדכון המהווה החמרה - מודגש **בצהוב**.
בעלונים קיימים עדכונים נוספים שאינם מהווים החמרה.
למידע מלא על התרופה יש לעיין בעלון לרופא המאושר.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: לונדבק בע"מ, דרך השלום 4, תל אביב.

בכבוד רב,

רבקה סלונים
רוקחת ממונה
לונדבק ישראל בע"מ

העלון לרופא עודכן בסעיפים הבאים:

4.4 Special warnings and precautions for use

Caution should be exercised in patients having: liver disease; cardiac disease, or arrhythmias; severe respiratory disease; renal failure; epilepsy (and conditions predisposing to epilepsy, e.g. alcohol withdrawal or brain damage); Parkinson's disease; narrow angle glaucoma; prostatic hypertrophy; hypothyroidism; hyperthyroidism; myasthenia gravis; pheochromocytoma and patients who have shown hypersensitivity to thioxanthenes or other antipsychotics.
[...]

Like other neuroleptics, zuclopenthixol acetate should be used with caution in patients with organic brain syndrome, convulsions or advanced hepatic, renal or cardiovascular disease.

Blood dyscrasias have been reported rarely. Blood counts should be carried out if a patient develops signs of persistent infection.



[...]

Older people

Older people require close supervision because they are especially prone to experience such adverse effects as sedation, hypotension, confusion, and temperature changes.

[...]

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Zuclopenthixol may potentiate the effects of general anaesthetics and anticoagulants and prolong the action of neuromuscular blocking agents.

The anticholinergic effects of atropine or other drugs with anticholinergic properties may be increased.

Concomitant use of drugs such as metoclopramide, piperazine or antiparkinson drugs may increase the risk of extrapyramidal effects such as tardive dyskinesia.

Combined use of antipsychotics and lithium or sibutramine has been associated with an increased risk of neurotoxicity.

Antipsychotics may enhance the cardiac depressant effects of quinidine; the absorption of corticosteroids and digoxin.

The hypotensive effect of vasodilator antihypertensive agents such as hydralazine and α blockers (e.g. doxazosin), or methyl-dopa may be enhanced.

[...]

Antipsychotics may also impair the effect of levodopa, adrenergic drugs and anticonvulsants.

The metabolism of tricyclic antidepressants may be inhibited and the control of diabetes may be impaired.

Since zuclopenthixol is partly metabolised by CYP2D6 concomitant use of drugs known to inhibit this enzyme may lead to higher than expected plasma concentrations of zuclopenthixol, increasing the risk of adverse effects and cardiotoxicity.

4.7 Effects on ability to drive and use machines

[...]

Alertness may be impaired, especially at the start of treatment, or following the consumption of alcohol; patients should be warned of this risk and advised not to drive or operate machinery until their susceptibility is known.

Patients should not drive if they have blurred vision.

4.8 Undesirable effects

[...]

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs – Frequency unknown.

[...]

4.9. Overdose

Symptoms: somnolence, coma, extrapyramidal symptoms, convulsions, hypotension,

[...]

There is no specific antidote.