

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך _____ January 11, 2015 _____

שם תכשיר באנגלית ומספר הרישום

ZYLET Ophthalmic Suspension

142 61 31618 00

שם בעל הרישום _סלומון, לוי, ואלשטיין בע"מ, ת.ד. 3696, פ"ת

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
		contraindications
		Posology, dosage & administration
<p>Safety and effectiveness in pediatric patients have not been established.</p> <p>Two trials were conducted to evaluate the safety and efficacy of Zylet® (loteprednol etabonate and tobramycin ophthalmic suspension) in pediatric subjects age zero to six years; one was in subjects with lid inflammation and the other was in subjects with blepharoconjunctivitis.</p> <p>In the lid inflammation trial, Zylet with warm compresses did not demonstrate efficacy compared to vehicle with warm compresses. Patients received warm compress lid treatment plus Zylet or vehicle for 14 days. The majority of patients in both treatment groups showed reduced lid inflammation.</p> <p>In the blepharoconjunctivitis trial, Zylet did not demonstrate efficacy compared to vehicle, loteprednol etabonate ophthalmic suspension, or tobramycin ophthalmic solution. There was no difference between treatment groups in mean change from baseline blepharoconjunctivitis score at Day 15.</p> <p>There were no differences in safety assessments between the treatment groups in either trial.</p>	<p>Safety and effectiveness in pediatric patients have not been established.</p>	<p>Special Warnings and Special Precautions for Use</p>
		Interaction with Other Medicaments and Other Forms of Interaction
		pregnancy and Fertility, Lactation
		Effects on ability to drive and use machines
		Adverse events