הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך 02.04.2015

שם תכשירים באנגלית ומספרי הרישום

VASODIP 10, TABLETS (109 87 29303)

VASODIP 10, TABLETS (130 24 30881)

שם בעל הרישום דקסל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
		Indication
		contraindications
		Posology, dosage & administration
		Special Warnings and Special Precautions for use
		Interaction with Other medicaments and Other Forms of Interaction
Pregnancy Data for lercanidipine provide no evidence of a teratogenic effect in the rat and the rabbit and reproductive performance in the rat was unimpaired. Nevertheless, since there is no clinical experience with lercanidipine in pregnancy and lactation, and other dihydropyridine compounds have been found teratogenic in animals, Vasodip should not be administered during pregnancy or to women with child-bearing potential unless effective contraception is used. ~~Because of high lipophilicity of lercanidipine, distribution in milk may be expected.~~ Breast-feeding It is unknown whether lercanidipine/metabolites are excreted in human milk. A risk in the newborns/infants cannot be excluded. Vasodip is contraindicated during breastfeeding (see section 4.3). Fertility No clinical data are available with lercanidipine. Reversible biochemical changes in the head of spermatozoa which can impair fecundation have been reported in some patients treated by channel blockers. In cases where repeated in-vitro fertilisation is	Data for lercanidipine provide no evidence of a teratogenic effect in the rat and the rabbit and reproductive performance in the rat was unimpaired. Nevertheless, since there is no clinical experience with lercanidipine in pregnancy and lactation, and other dihydropyridine compounds have been found teratogenic in animals, Vasodip should not be administered during pregnancy or to women with child-bearing potential unless effective contraception is used. Because of high lipophilicity of lercanidipine, distribution in milk may be expected. Therefore, it should not be administered to nursing mothers.	**Pregnancy and Fertility, Lactation**

<table>
<tr><td>unsuccessful and where another explanation cannot be found, the possibility of calcium channel blockers as the cause should be considered.</td><td></td><td></td></tr>
<tr><td></td><td></td><td>Adverse events</td></tr>
<tr><td>~~Clinical experience with lercanidipine indicates that it is unlikely to impair a patient's ability to drive or use machinery.~~ Vasodip has minor influence on the ability to drive and use machines. However, caution should be exercised because dizziness, asthenia, fatigue and rarely somnolence may occur.</td><td>Clinical experience with lercanidipine indicates that it is unlikely to impair a patient's ability to drive or use machinery. However, caution should be exercised because dizziness, asthenia, fatigue and rarely somnolence may occur.</td><td>Effects on ability to drive and use machines</td></tr>
<tr><td>In the post-marketing experience, some cases of overdose were reported (~~150 mg, 280 mg and~~ from 40 up to 800 mg of lercanidipine ~~-~~including reports of suicide attempt).
<table><tr><th>~~Dose level~~</th><th>~~Signs/symptoms~~</th><th>~~Management~~</th><th>~~Outcome~~</th></tr><tr><td>~~150 mg + unidetified amount of alcohol~~</td><td>~~Sleepiness~~</td><td>~~Gastric lavage, active charcoal~~</td><td>~~recovered~~</td></tr><tr><td>~~280 mg + 5.6 mg moxonidine~~</td><td>~~Cardiogenic shock severe myocardial ischemia mild renal failure~~</td><td>~~High dose catacholaminnes Furosamide Digitalis Parenteral plasma expanders~~</td><td>~~recovered~~</td></tr><tr><td>~~800 mg~~</td><td>~~Emesis Hypotenstion~~</td><td>~~active charcoal cathartics Dopamine I.V.~~</td><td>~~Recovered~~</td></tr></table>…..</td><td>In the post-marketing experience, three cases of overdose were reported (150 mg, 280 mg and 800 mg of lercanidipine, respectively, ingested in an attempt to commit suicide).
<table><tr><th>Dose level</th><th>Signs/symptoms</th><th>Management</th><th>Outco</th></tr><tr><td>150 mg + unidetified amount of alcohol</td><td>Sleepiness</td><td>Gastric lavage, active charcoal</td><td>recove</td></tr><tr><td>280 mg + 5.6 mg moxonidine</td><td>Cardiogenic shock severe myocardial ischemia mild renal failure</td><td>High dose catacholaminnes Furosamide Digitalis Parenteral plasma expanders</td><td>recove</td></tr><tr><td>800 mg</td><td>Emesis Hypotenstion</td><td>active charcoal cathartics Dopamine I.V.</td><td>Recov</td></tr></table>…..</td><td>Overdose</td></tr>
<tr><td>Non-clinical data reveal no special hazard for human based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.
Safety pharmacological studies in animals have shown no effects on the autonomic nervous system, the central nervous system or on gastrointestinal function at antihypertensive doses.

…..</td><td>Safety pharmacological studies in animals have shown no effects on the autonomic nervous system, the central nervous system or on gastrointestinal function at antihypertensive doses.

…..</td><td>Pre-clinical safety data</td></tr>
</table>

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פרק בעלון	טקסט נוכחי	טקסט חדש
התוויות		
מתי אין להשתמש בתכשיר?	▪ הנך בהריון או מניקה.	▪ הנך בהריון או מניקה, חושבת שאת בהריון או מתכננת הריון או שאינך משתמשת באמצעי מניעה. ....
אזהרות מיוחדות הנוגעות לשימוש בתרופה		
אין להשתמש בתרופה מבלי להיוועץ ברופא לפני התחלת הטיפול		
תגובות בין תרופתיות		
הריון והנקה	אין להשתמש בתרופה אם הינך בהיריון, או מניקה.	אין להשתמש בתרופה אם הינך בהיריון, או מניקה, חושבת שאת בהריון או מתכננת הריון או שאינך משתמשת באמצעי מניעה.
כיצד תשתמש בתרופה?		
תופעות לוואי		