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# הודעה על החמרה ( מידע בטיחות) בעלון לצרכן

# (מעודכן 05.2013)

**תאריך:** 26/05/2015

**שם תכשיר באנגלית ומספר הרישום:** DOMITOR VETERINARY 082 58 92306 00

**שם בעל הרישום:** זואטיס ישראל הולדינג בי.וי

טופס זה מיועד לפרוט ההחמרות בלבד !

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **התוויות** |  |  |
| **מתי אין להשתמש בתכשיר?** |  |  |
| **אזהרות מיוחדות הנוגעות לשימוש בתרופה:** | **הנחיות והוראות בטיחות לאדם הנותן תרופה לחיה:**  יש לשטוף את העיניים במים זורמים ~~למשך כ-15דקות.~~  במידה של בליעה או הזרקה של התרופה – יש לפנות לקבלת טיפול רפואי ~~ולהציג תווית התכשיר.~~  ~~אנשים הסובלים ממחלות לב וכלי דם (כגון יתר לחץ דם, מחלת לב ספיקתית, וכד' ) – עליהם לנקוט משנה זהירות בשימוש בתרופה על מנת למנוע חשיפה אליה.~~ | **Special precautions for use**  i. Special precautions for use in animals  A clinical examination should be carried out in all animals before the use of drugs for sedation and/or general anaesthesia.  Care should be taken when using Domitor in animals with cardiovascular disease.  Care should be taken when combining medetomidine with other anaesthetics or sedatives. Before using any combinations consult the contraindications and warnings that appear on the concomitant product’s data sheet.  Special care is recommended when treating very young animals and older animals.  Domitor, ketamine and propofol are metabolised in the liver and excreted primarily via the kidneys. Pre-existing liver or kidney pathology should be carefully evaluated to confirm adequate function prior to using these products.  In cats, when Domitor is used in combination with ketamine, laryngeal and pharyngeal reflexes are retained during anaesthesia  ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals.  In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur.  Avoid skin, eye or mucosal contact.  Remove contaminated clothes that are in direct contact with skin.  If pregnant women handle the product, special caution should be observed not to self inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.  **Advice to Doctors:**  Medetomidine hydrochloride is an alpha-2 adrenoreceptor agonist. Symptoms after absorption may involve clinical effects including dose dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. |
| **אין להשתמש בתרופה מבלי להיוועץ ברופא לפני התחלת הטיפול:** |  |  |
| **תגובות בין תרופותיות:** |  | Medetomidine must not be mixed with other products, with the exception of Vetalar and Ketaset Injection and Torbugesic injection. |
| **הריון והנקה:** |  |  |
| **כיצד תשתמש בתרופה:** |  | An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. |
| **תופעות לוואי:** |  | Blood pressure will increase initially and then return to normal or slightly below normal. Cyanosis has been reported.  Some animals experience muscle tremors and may be sensitive to loud sounds.  Incidents of prolonged sedation and recurrence of sedation after initial recovery have been reported.  Isolated cases of hypersensitivity, paradoxical response (excitation) and lack of efficacy have been reported.  Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported.  If the animal has a pre-existing subclinical respiratory disease, administration of Domitor can cause some significant respiratory depression which could predispose the animal to cardiac arrest. Pulmonary oedema has been reported.  The combination of Domitor and ketamine is reported to elicit a pain response in some cats when administered intramuscularly. Heart rates will generally decrease to approximately 50% of pre-anaesthetic levels and in some cats very slow respiratory rates are observed (4-6 breaths per minute).  In dogs, when Domitor is used in combination with propofol, movement of the forelegs may occur during induction of anaesthesia. In some cases at higher dosages, a decline in arterial oxygen tension may occur. |
| **מינון יתר:** | ~~מחקרים הראו, שהחיות סובלות מינונים עד פי 5 מהמינון המומלץ במתן IV ועד פי 10 במתן IM.~~ |  |

**מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב**.