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

תאריך 22/04/2014

שם תכשיר באנגלית ומספר הרישום Ventavis 133-14-31070-00

שם בעל הרישום באייר ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
4) **תופעות לוואי**		במקרים נדירים מאוד דווח על דימום מוחי ותוך גולגלתי מסכני חיים. תופעות לוואי שכיחות (תופעות שמופיעות לכל היותר במטופל אחד מתוך 10 מטופלים): – ירידה בלחץ הדם תופעות לוואי שכיחות (תופעות שמופיעות לכל היותר במטופל אחד מתוך 10 מטופלים): – עליה בקצב לב – תחושה של קצב לב מהיר או חזק (פלפיטציות)

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

תאריך 09/04/2014

שם תכשיר באנגלית ומספר הרישום Ventavis 133-14-31070-00

שם בעל הרישום באייר ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**

The use of Ventavis is not recommended in patients with unstable pulmonary hypertension, with advanced right heart failure. In case of deterioration or worsening of right heart failure transfer to other medicinal products should be considered. Hypotension Blood pressure should be checked while initiating Ventavis. In patients with low systemic blood pressure and in patients with postural hypotension or receiving medicinal products known to reduce blood pressure levels, care should be taken to avoid further hypotension. Ventavis should not be initiated in patients with systolic blood pressure less than 85 mmHg. Physicians should be alerted to the presence of concomitant conditions or medicinal products that might increase the risk of hypotension and syncope (see section 4.5). Interruption of therapy In case of interruption of Ventavis therapy, the risk of rebound effect is not formally excluded. Careful monitoring of the patient should be performed, when inhaled iloprost therapy is stopped and an alternative treatment should be considered in critically ill patients. Serum glucose levels Prolonged oral treatment with iloprost clathrate in dogs up to one year was associated with slightly increased fasted serum glucose levels. It cannot be excluded that this is also relevant to humans on prolonged Ventavis therapy. Undesirable exposure to Ventavis To minimise accidental exposure, it is recommended to use Ventavis with nebulisers with inhalation-triggered systems (such as HaloLite/Prodose, I-Neb), and to	Ventavis solution for inhalation should not come into contact with skin and eyes; oral ingestion of Ventavis solution should be avoided. During nebulization sessions a facial mask must be avoided and only a mouthpiece should be used. Prolonged oral treatment with iloprost clathrate in dogs up to one year	**4.4 Special warnings and precautions for use**

keep the room well ventilated. Newborns, infants, and pregnant women should not be subjected to Ventavis in the room air. Skin and eye contact, oral ingestion Ventavis nebuliser solution should not come into contact with skin and eyes; oral ingestion of Ventavis solution should be avoided. During nebulisation sessions a facial mask must be avoided and only a mouthpiece should be used.		
Since iloprost inhibits platelet function its use with anticoagulants (such as heparin, coumarin-type anticoagulants) or other inhibitors of platelet aggregation (such as acetylsalicylic acid, non-steroidal anti-inflammatory medicinal products, ticlopidine, clopidogrel, glycoprotein IIb/IIIa antagonists: abciximab, eptifibatide and tirofiban) may increase the risk of bleeding	Since iloprost inhibits platelet function its use with anticoagulants (such as heparin, coumarin-type anticoagulants) or other inhibitors of platelet aggregation (such as acetylsalicylic acid, non-steroidal anti-inflammatory medicinal products, phosphodiesterase inhibitors and nitro vasodilators) may increase the risk of bleeding	**4.5 Interaction with other medicinal products and other forms of interaction**
Cardiac disorders Tachycardia, Palpitations **General disorders and administration site condition** Peripheral oedema§ Description of selected adverse reactions Fatal cases included cerebral and intracranial haemorrhage.		**4.8 Undesirable effects**