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רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

Isoflurane USP Terrell

חברת פרמה מדיס בע"מ מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

General inhalation anesthetic

מרכיב פעיל: ISOFLURANE 100%
צורת המתן של התכשיר: INHALATION

להלן העדכונים העיקריים בעלון לצרכן (במתכונת עלון לרופא):

4.4 Special warnings and precautions for use

There is insufficient experience of use in repeated anaesthesia to make a definitiverecommendation in this regard. As with all halogenated anaesthetics repeat anaesthesia within a short period of time should be approached with caution.

In light of the fact that Isoflurane acts in an irritating manner on the mucous membranes, the product is difficult to use if inhalation anaesthesia is applied via mask.

Increased blood losses comparable with those found following anaesthesia with otherinhalation agents have been recorded with isoflurane in patients undergoing induced abortion.

Malignant hyperthermia

An increase in overall metabolism may be reflected in an elevated temperature (which may rise rapidly early or late in the case, but usually is not the first sign of augmented metabolism) and an increased usage of the CO₂ absorption system (hot canister)

4.5 Interaction with other medicinal products and other forms of interaction

Combinations requiring precautions in using:

- Beta-blockers: Concomitant use of beta blockers may exaggerate the

cardiovascular effects of inhalational anesthetics, including hypotension and negative inotropic effects. Risk of blockage of the cardiovascular compensation mechanism, as a result of which negative inotropic effects are intensified. The action of beta-blockers can be suppressed during the operation with the use of beta-sympathomimetic agents. In general, any medication with a beta-blocker need not be stopped and an abrupt reduction of the dosage should be avoided.

- Isoniazid: Risk of potentiating the hepatotoxic effect, with increased formation of toxic metabolites of isoniazid. Treatment with isoniazid should be suspended one week before the operation and should not be resumed until 15 days afterwards.
- Epinephrine (adrenaline) by sub-cutaneous or gingival injections: risk of serious ventricular arrhythmia as a consequence of increased heart rate, although the myocardial sensitivity with respect to epinephrine is lower with the use of isoflurane than in the case of halothane. Thus, the dosage should be limited to, for example, 0.1 mg epinephrine within 10 minutes or 0.3 mg within one hour in adults. Doses of adrenaline greater than 5 mcg/kg, when administered submucosally, may produce multiple ventricular arrhythmias.

-Thus it is recommended that approximately one third to one half of the usual dose of these substances be administered. The disappearance of the myoneural effect takes longer with isoflurane than with other conventional anaesthetics.

4.8 Undesirable effects

Summary of Most Frequent Adverse Drug Reactions		
Investigations	Not known	Blood creatine phosphokinase increased

4.9 Overdose

In case of overdosage, stop administration of the anaesthetic agent.

השינויים המודגשים ברקע צהוב מהווים החמרה. בעלון בוצעו שינויים נוספים אשר מהווים תוספת מידע.



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העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://israeldrugs.health.gov.il/#!/byDrug>
ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת פרמה מדיס בע"מ, פייירברג 4 חולון.

בברכה,

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