רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של:
FOSCAVIR 24 MG/ML

Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS).

<u>להלן העדכונים העיקריים:</u>

4.4 Special Warnings and Precautions for Use

This medicinal product contains 1.38 g of sodium per 250 ml bottle, equivalent to equivalent to 69% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
The maximum recommended daily dose of this product is 12 g of Foscavir 24mg/ml per day (180 mg/kg/day in average 70 kg male), which is equivalent to 138% of the WHO recommended maximum daily dietary intake for sodium.
Foscavir 24mg/ml is considered high in sodium. This should be particularly taken into account for those on a low sodium diet. Its use should be avoided when a saline load cannot be tolerated (e.g. in cardiomyopathy).
Foscarnet has been associated with cases of prolongation of QT interval and more rarely with cases of torsade de pointes (see section 4.8). Patients with known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances (hypokalaemia, hypomagnesaemia), bradycardia, as well as patients with underlying cardiac diseases such as congestive heart failure or who are taking medications known to prolong the QT interval should be carefully monitored due to increased risk of ventricular arrhythmia. Patients should be advised to promptly report any cardiac symptoms.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

Due to the potential increased risk of QT prolongation and torsade de pointes, Foscavir should be used with caution with drugs known to prolong QT interval, notably class IA (e.g. quinidine) and III (e.g. amiodarone, sotalol), antiarrhythmic agents or neuroleptic drugs. Close cardiac monitoring should be performed in cases of co-administration.

4.8 Undesirable Effects

- **Blood and lymphatic system disorders** – Pancytopenia (Frequency**:** Uncommon)
- **Immune system disorders** - Hypersensitivity (including anaphylactic reactions), anaphylactoid reactions (Frequency**:** Not known)
- **Metabolism and nutrition disorders** - hypercalcaemia, dehydration (Frequency**:** Common), Hypernatraemia (Frequency: Not known)
- **Cardiac disorders** – tachycardia (Frequency**:** Common), torsade de pointes (Frequency: Not known)
- **Gastrointestinal disorders** - gastrointestinal haemorrhage (Frequency**:** Common)
- **Skin and subcutaneous disorders** - Urticaria, angioedema (Frequency**:** Uncommon), Erythema multiforme, toxic epidermal necrolysis, Stevens Johnson syndrome (Frequency: Not known)
- **Renal and urinary disorders** – proteinuria (Frequency: Common), Glomerulonephritis, nephrotic syndrome (Frequency**:** Uncommon), haematuria (Frequency: Not known)
- **General disorders and administration site conditions** - chest pain, injection site pain, injection site inflammation (Frequency**:** Common), Extravasation (Frequency: Not known)
- **Investigations** - gamma-glutamyltransferase increased, alanine aminotransferase increased, aspartate aminotransferase increased, lipase increased (Frequency**:** Common)

6.3 Shelf-Life

The expiry date of the product is indicated on the packaging materials

6.4 Special Precautions for Storage

Do not store above 25°C.

העלון לרופא/לצרכן מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
דיויד וגנר
רוקח ממונה