

הודעה על החמרה (מידע בטיחות) בעלון לרופא

טופס זה מיועד לפרוט החמרות בלבד, מעודכן מאי 2015

תאריך 2 Nov 2015

שם תכשיר באנגלית Kiovig 100 mg/ ml Solution for Infusion

מספר הרישום 146-45-33157

שם בעל הרישום Teva Medical Marketing Ltd

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>In all patients, IVIg administration requires:</p> <ul style="list-style-type: none"> adequate hydration prior to the initiation of the infusion of IVIg monitoring of urine output monitoring of serum creatinine levels monitoring for signs and symptoms of thrombosis assessment of blood viscosity in patients at risk for hyperviscosity avoidance of concomitant use of loop diuretics. <p>[...]</p> <p><u>Thromboembolism</u></p> <p>... Caution should be exercised in prescribing and infusion of IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, hypertension, use of estrogens, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, hypercoagulable disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity, patients with indwelling vascular catheters and patients with high dose and rapid infusion).</p> <p>[...]</p> <p><u>Acute renal failure</u></p> <p>... In most cases, risk factors have been identified, such as pre-existing renal insufficiency, diabetes mellitus, hypovolemia, overweight, concomitant nephrotoxic medicinal products, age over 65, sepsis, hyperviscosity or paraproteinemia.</p> <p>[...]</p> <p><u>Interference with serological testing</u></p> <p>[...]</p>	<p>In all patients, IVIg administration requires:</p> <ul style="list-style-type: none"> adequate hydration prior to the initiation of the infusion of IVIg monitoring of urine output monitoring of serum creatinine levels avoidance of concomitant use of loop diuretics. <p>[...]</p> <p><u>Thromboembolism</u></p> <p>... Caution should be exercised in prescribing and infusion of IVIg in obese patients and in patients with pre-existing risk factors for thrombotic events (such as a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, hypercoagulable disorders, patients with prolonged periods of immobilisation, severely hypovolemic patients, patients with diseases which increase blood viscosity).</p> <p>[...]</p> <p><u>Acute renal failure</u></p> <p>... In most cases, risk factors have been identified, such as pre-existing renal insufficiency,</p>	<p>Special Warnings and Special Precautions for Use</p>

Administration of KIOVIG can lead to false positive readings in assays that depend on detection of beta-D-glucans for diagnosis of fungal infections. This may persist during the weeks following infusion of the product

diabetes mellitus, hypovolemia, overweight, concomitant nephrotoxic medicinal products, age over 65, sepsis, or paraproteinemia.

Decreased appetite – Common
Hypertension - Very common
Dyspnea – Common
Dyspepsia – Common
Abdominal distension – Uncommon
Rash - Very common
Contusion, dermatitis, erythema – Common

Hypertension – Common
Dyspnea – Uncommon

Adverse events

Arthralgia – Common
Local reactions (e.g. infusion site pain/swelling/reaction/pruritus – Very common
Chills, edema – common
burning sensation – Uncommon
white blood cell count decreased, alanine aminotransferase increased – Uncommon
cerebral vascular accident - Not known

Rash – Common
Pruritus, urticaria, erythematous rash, pruritic rash – Common

infusion related reaction – Uncommon