Ohutusalane teabekiri

Metamisool - ravimindutseeritud maksakahjustuse risk

1.12.2020

Lp arstid

Metamisooli kasutamisega seoses on teatatud ravimindutseeritud maksakahjustuse (*drug-induced liver injury, DILI*) tekkest.

Metamisooli vajavale patsiendile tuleb selgitada, kuidas ära tunda maksakahjustuse nähte (nahakollasus, tume uriin, iiveldus, oksendamine) ja seda, et nende nähtude tekkimisel tuleks ravi koheselt peatada ja võtta ühendust arstiga maksaanalüüside tegemiseks.

Teatatud juhtudel oli maksakahjustus peamiselt hepato-tsellulaarset tüüpi ja algas mõni päev kuni kuu ravi alustamisest.

Maksakahjustus tekkis sageli muu raviga seotud ülitundlikkuse (nt nahalööve, veredüskraasiad, palavik ja eosinofiilia) või autoimmuunse hepatiidi foonil.

Mõnel patsiendil tekkis maksakahjustus uuesti ravi taasalustamisel. Välistada ei saa immuun-allergilist mehhanismi.

Kui patsiendil tekkinud maksakahjustust seostatakse metamisooliga, siis ei tohi tal enam metamisooli uuesti kasutama hakata.

Vaatamata sellele, et metamisoolil puudub Eestis müügiluba, andke palun tõsistest kõrvaltoimetest Ravimiametile teada – www.ravimiamet.ee – teata kõrvaltoimest.

Taustateave inglise keeles:

Metamizole is a non-opioid pyrazolone derivative with potent analgesic, antipyretic and weak anti-inflammatory properties.

Recently identified new information on liver injury prompted a full review of data in association with the potential of metamizole to cause DILI. During the review, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) considered information from all available sources including adverse drug reaction reports and studies published in the scientific literature.

Liver injury was observed to be predominantly of a hepatocellular pattern with an onset of a few days to months following treatment initiation. Signs and symptoms included elevated serum hepatic enzymes with or without jaundice, frequently in the context of other drug hypersensitivity reactions (e.g., skin rash, blood dyscrasias, fever and eosinophilia) or accompanied by features of autoimmune hepatitis. In some patients, liver injury recurred upon re-administration.

The mechanism of metamizole-induced liver injury is not clearly elucidated, but available data indicate an immuno-allergic mechanism.

In general, drug-induced liver injury may progress to potentially serious outcomes, such as acute hepatic failure requiring liver transplantation.

Based on the cumulative marketing experience with metamizole of almost 100 years and the extent of patient exposure to the medicine, the occurrence of liver injury due to metamizole is thought to be very rare, but the exact frequency cannot be calculated.

Early recognition of potential liver injury from metamizole use is essential. Patients should be educated to be vigilant for symptoms of potential liver injury and be encouraged to stop the use of metamizole and see a doctor if such symptoms arise. Healthcare Professionals are advised to assess and monitor liver function in patients presenting with signs and symptoms suggestive of any liver injury.

Re-exposure to metamizole is not recommended in case of a prior liver injury episode that occurred during metamizole treatment, for which no other cause of liver injury has been determined.

Täiendav info: info@ravimiamet.ee