



## The Evidence of Mefenamic Acid is Unsafe and ICP Issues Safety Alert

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Mefenamic acid is a fenamic acid derivative of carboxylic acid, and is available worldwide as tablets (250 and 500mg), capsules (250mg) and a paediatric suspension (50 mg/5ml). Clinical Effects in Overdose Mefenamic acid is the fifth most commonly prescribed NSAID and is a common source of selfpoisoning: 8.5% of all NSAID overdoses reported in one study between 1971 and 1985 were due to mefenamic acid (McMurray, et al. 1987).

The most serious symptoms in overdose have involved the CNS, with seizures being a common finding. Which leads to metabolic acidosis, cardiac arrest, coma and acute renal failure. Furthermore, various gastrointestinal irritant effects are also seen.

Neurological. Coma or a depressed convulsions was noted in cases of mefenamic acid overdose reported by Gossinger, et al. (1982) and Turnbull, et al. (1988). In the Gossinger case, a 13-year-old patient ingested 5 to 109 and became unconscious within 1.5 hours but did not experience seizures until later. She began to recover within 45 minutes and was normal within 12 hours. Irritability, restlessness and agitation may lead to seizures (Balai-Mood, et al. 1981). A dose of mefenamic acid 12.5g produced status epilepticus in a 19-year-old patient approximately 3 hours after ingestion (Young 1979). A single seizure was also seen in each of 2 teenage girls who ingested 25 to 50g; their plasma concentrations were 110 and 72 mg/L, compared with a normal therapeutic range of < 10 mg/L (Robson, et al. 1979). More than one-third of all patients with a confirmed mefenamic acid overdose develop seizures (Prescott, et al. 1981), often not until 12 to 20 hours after ingestion (Court and Volans 1984).

A transient respiratory arrest occurred after a convulsion in a 15-year-old patient who was thought to have ingested about 7.5g

of mefenamic acid. She had recovered by the next day (Court and Volans 1984). Drug Sa/ely 5 (4) 1990 17.2 Case Report A 30-year-old male was seen after ingesting 12.5g of mefenamic acid. Initially there was restlessness and agitation, which progressed to generalised tonic-clonic convulsions. The patient was paralysed with neuromuscular blocking agents, intubated, and lavaged. Seizures were treated with diazepam and chlormethiazole. About 24 hours after ingestion, the patient developed abdominal pain, vomiting, increased serum creatinine and bloody diarrhoea, but remained normotensive and well hydrated. The serum creatinine peaked 5 days after ingestion at 804 mmol/L. Four days after admission he developed loin pain and microscopic haematuria. Mefenamic acid concentrations were 46 mg/L on admission, 4 mg/L 21 hours later, and undetectable within 27 hours. The patient recovered with conservative therapy (Turnbull, et al. 1988).

Seizures and cardiopulmonary arrest occurred in a 19-year-old patient with a concentration of 51 mg/L (Frank, et al. 1983). Coma resulted in one 13-year-old patient, with a blood concentration of 21 mg/L at 4 hours after ingestion (Gossinger, et al. 1982) [1].

The inclination of mefenamic acid overdose to induce central nervous system (CNS) toxicity, particularly seizures, has been reported in a number of case reports and case series but the differential neurotoxicity of individual NSAIDs, in overdose and normal use, and the influence of other risk factors on the development of neurotoxicity have not previously been reported.

Between January 2007 and December 2013, About 23 144 NPIS telephone enquiries relating to 22 937 separate exposures to the four NSAIDs studied. Which exposures were less common for mefenamic acid (925) than for ibuprofen (17 302), diclofenac (3385)

or naproxen (1325). The median age of mefenamic acid group was younger (17 years) than in enquiries about ibuprofen (23 years), diclofenac (29 years) or naproxen (32 years) and there was a significantly higher proportion of female patients in mefenamic acid group compared with the other combined groups [2].

The comparative study which consisting of 50 patients complaining of menorrhagia randomized into two groups 24 patients in group A (mefenamic acid) and 26 patients in group B (tranexamic acid) was studied to know the efficacy, acceptability and safety of two drugs.

Both mefenamic acid and tranexamic acid were effective in management of menorrhagia. Tranexamic acid was better than mefenamic acid in terms of reduction in menstrual blood loss. The mefenamic acid and Tranexamic acid have the advantage of only being administered during menstruation. Control of dysmenorrhoea was attained in significant number of patients in both groups. Unimportant side effects like epigastric pain, nausea, vomiting was more frequent in mefenamic acid group and Tolerance rate was high in both groups [3].

Further more in the recent times the Indian Pharmacoeia Commission (IPC) passed a drug safety alert about Mefenamic acid NSAID painkiller, Which can cause adverse reactions, including drug reactions with eosinophilia and systemic symptoms (DRESS) syndrome.

The commission, in its alert, says that a primary analysis of adverse drug reactions from the Pharmacovigilance Programme of India (PvPI) database reported DRESS syndrome. DRESS syndrome which is a severe allergic reaction caused by certain medicines with higher doses . Leads reactions include skin rash, fever and lymphadenopathy, which can occur between two and eight weeks after administration the drug.