Statement

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IAP Committee for Protection of Child Consumer: Statement on Safety of Nimesulide in Children

Recently media (Television and Newspapers) have suggested that Nimesulide, a commonly used antipyretic and analgesic, may not be a safe drug, especially for children. The Committee for Protection of Child Consumer (CPCC) was therefore requested by the Executive Board of IAP to deliberate on the issue and to make specific recommendations regarding the safety of using this drug in children. The following sources and methods were utilized by the Committee to formulate this Consensus Statement: (*i*) Non-funded meta-analysis of 16 randomized controlled trials including 1254 children, which was conducted to specifically resolve this controversy(1); (*ii*) Review of other published literature on the subject; (*iii*) Opinions of the speakers, faculty and delegates during a specific session on this issue in the Indo-UK Symposium on "Hot Topics in Pediatrics" on February 1, 2003; (*iv*) Discussions with some of the doctors who had expressed reservations about usage of Nimesulide in the local press; (*v*) Circulation of the draft recommendations to members of the Committee unable to participate in the Symposium (all members listed in *Appendix I*). The statement was not intended to and nor does it attempt to guide preferential use of one analgesic-antipyretic over another. To retain scientific indepen-dence, no funding was taken from any source for formulating this statement.

Consensus Statement

• For short-term (<10 days) use in children, Nimesulide is **as "safe" or "unsafe" as other analgesic-antipyretics**. There is no significant increase(1) in the risk of hypothermia, gastrointestinal bleeding, epigastric pain, vomiting, diarrhea and transient asymptomatic hepatic enzyme elevation with Nimesulide as compared to the control groups (Paracetamol, Placebo, or other non-steroidal anti-inflammatory drugs like Ibuprofen, Mefenamic Acid, Salicylates).

• Nimesulide ingestion, similar to other non-steroidal anti-inflammatory drugs (NSAIDs), has been associated with rare and unpredictable but serious hepatic adverse reactions. The estimated incidence (all ages) of 1 per 1 million treated patients (lower than or comparable to other non-steroidal anti-inflammatory drugs) suggests that rare cases of such liver injury may be caused by a metabolic idiosyncrasy. Further, the published "Case Reports" of serious hepato-toxicity are mostly restricted to prolonged usage (reported mean 2 months) and adults (reported mean age 62 years)

• Administration of Nimesulide, like other NSAIDs should be **avoided in known or suspected liver disease** or with the use of other hepato-toxic drugs.

• There is limited data for drawing concrete inferences **below the age of six months** (as for other NSAIDs).

• To prevent over dosage, particularly in view of the higher concentration, taste and relatively longer half-life of the drug, clinicians should prescribe the exact syrup dosage in milliliters and carefully explain the frequency of administration.

• The drug manufacturers should dilute the concentration of the syrup to reduce the possibility of over dosage. A warning about its risk of over dosage should be mentioned clearly.

(Practice of medicine is dynamic. Any set of recommendations can be modified with further scientific evidence. Please do let us know of any adverse effects of any drug or vaccine you come across - Dr. S.C. Arya, Chairman, IAP Committee for Protection of Child Consumer, B-453, New Friends Colony, New Delhi 110 065, India. E-mail: scaryanfc@yahoo.com)

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REFERENCES

1. Gupta P, Sachdev HPS. Safety of oral use of Nimesulide in children: Systematic review of randomized conrolled trials. Indian Pediatr 2003; 40: 518-531.