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Generic Name:

Ibuprofen

Trade Name:

Infants? Ibuprofen Concentrated Oral Suspension

Company:

Tris Pharma

Notes:

Tris Pharma has [voluntarily recalled](#) three lots of Infants? Ibuprofen Concentrated Oral Suspension, 50 mg per 1.25 mL, to the retail level. The recalled lots may contain higher concentrations of ibuprofen.

There is a remote possibility that infants, who may be more susceptible to a higher potency level of drug, may be more vulnerable to permanent NSAID-associated renal injury. Adverse effects that may be experienced are nausea, vomiting, epigastric pain, or more rarely, diarrhea. Tinnitus, headache, and GI bleeding are also possible adverse effects. To date, Tris Pharma has not received any reports of adverse events related to this recall.

The product is used as a pain reliever/fever reducer and was packaged in 0.5 oz. bottles for the recalled lots listed [here](#).

Tris Pharma sold the affected lots to one customer, which distributed the lots into the U.S. market. Tris Pharma has notified its customer by urgent recall notice and is arranging for return of the recalled product.

Medication Monitor Categories:

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