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Generic Name:

Ibuprofen oral suspension drops

Trade Name:

No trade name

Company:

Tris Pharma

Notes:

Tris Pharma is [expanding](#) the scope of its November 2018 recall by adding three additional lots of ibuprofen oral suspension drops, 50 mg per 1.25 mL, to the retail (pharmacy) level. Some units from these batches have been found to have higher levels of Ibuprofen concentration.

Infants already susceptible to the adverse effects of ibuprofen may be at a slightly higher risk if they receive medication from one of the affected lots. There is a remote probability that infants, who may be more susceptible to a higher potency level of drug, may be more vulnerable to permanent NSAID-associated renal injury. Some units from these six lots have been found to contain ibuprofen as high as 10% above the specified limit. Studies have shown that safety issues or toxicity is generally accepted to be a concern in infants at doses in excess of 700% of the recommended dose.

To date, no serious adverse events have been reported related to this recall.

The product is used as a pain reliever/fever reducer and is packaged in 0.5-oz. and 1-oz. bottles. The affected lots can be found [here](#).

Medication Monitor Categories:

[Alerts and Recalls](#)

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