

Iron oxide particle found in Hospira vaccine

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Singapore: Hospira has issued a voluntary recall of one lot of preservative-free Bupivacaine HCl Injection, due to visible particles embedded and free floating within a single-dose glass teartop vial, identified as iron oxide.

The recall is being carried out to the user level including both human and veterinary.

Risk factors associated with particulate include the potential for particulate to be injected and/or therapy may be delayed. If smaller pieces of the particulate break off and become free floating within the solution, it may be injected into the patient. Injected particulate may result in local inflammation, low-level allergic or immune responses, granuloma formation or mechanical irritation of tissue, in particular in patients allergic or sensitive to iron oxide. In addition, therapy may be delayed if observation of particulate is not made until the point of care. This delay is likely to be of negligible clinical significance provided remediation is readily available.

The lot was distributed from July 2014 to September 2014. Hospira has not received reports of any adverse events associated with this issue for this lot to date.