

Agila recalls 10 lots of Etomidate injection in US

PRESS TRUST OF INDIA

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AGILA Specialties, now a part of Mylan, is recalling 10 lots of Etomidate injection, used in general anaesthesia in the US due to presence of small black particles in vials and inappropriate labeling.

The company, formerly a part of Bangalore-based Strides Acrolab and sold to Mylan Inc for a total consideration of up to \$1.75 billion last year, had initiated the nationwide voluntary recall on February 14.

"Agila Specialties is conducting a voluntary nationwide recall to the hospital/user level of 10 lots of Etomidate Injection 2 mg/ml - 10 ml and 20 ml," the US food and drug administration (USFDA) said on its website.

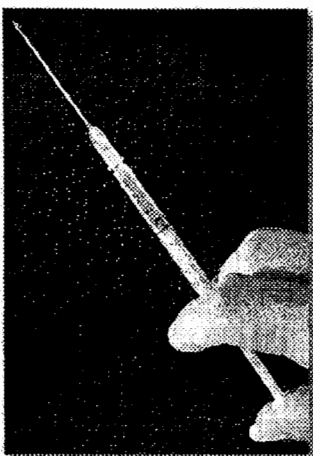
The 10 lots were manufactured by Agila Specialties Polska in Warsaw, Poland. All of the products bear a Pfizer label, it added.

Citing the reasons for the recall, the USFDA said it was "due to the potential for small black particles,

identified as paper shipper labels, to be present in individual vials; the potential for missing lot number and/or expiry date on the outer carton, and the potential for illegible/missing lot number and expiry on individual vials."

Intravenous administration of particles may lead to impairment of microcirculation, phlebitis, infection, embolism and subsequent infarction, it added.

Mylan and Pfizer have not received any reports of adverse events related to the recalled product to date, the USFDA statement said.



Total recall

- Etomidate is indicated for the supplementation of subpotent anesthetic agents
- Etomidate is a hypnotic drug without analgesic activity. It is indicated by intravenous injection
- Mylan and Pfizer have not received any reports of adverse events related to the recalled product

Etomidate is a hypnotic drug without analgesic activity. It is indicated by intravenous injection for the induction of general anaesthesia.

Etomidate is also indicated for the supplementation of subpotent anesthetic agents.

Etomidate is a carboxylated imidazole derivative that has anesthetic and amnestic properties, but that has no analgesic properties.

In emergency settings, etomidate is one of the most frequently used sedative hypnotic agents.

Agila