

महाराष्ट्र शासन
सह आयुक्त (पुणे विभाग)
अन्न व औषध प्रशासन म. राज्य,
७९१/९३, लकी बिल्डींग,
नवीन गुरुवार पेट,
पुणे-४११०४२
दुरध्वनी क्र. ०२०-२४४७०२७६



GOVERNMENT OF MAHARASHTRA
Office of Joint Commissioner (Pune Division)
Food & Drug Administration M. S.
791/93, Lucky Building,
New GuruwarPeth,
Pune- 411 042
Email –fdapunedrug@gmail.com
Phone No.: 020- 24470276

Out No . Drug/Orofer FCM Inj/252/2022 zone -6

dated 21/11/2022

Urgent

By email

To,

All concerned Drug Controller, all states of India

Sub: Drugs & Cosmetics Act 1940 & Rules thereunder

Regarding adverse drug reaction -INJ OROFER FCM (Ferric Carboxymaltose Injection 500 mg/10 ml) B. No. ELF8BB2001 MFG. Date: MAY 2022 Exp date 04/2025 MFG LIC NO. KD-675-A Manufactured by: Emcure Pharmaceuticals Ltd. MFD at J-174, J-168 & J-168/1, MIDC, Tarapur, Boisar, Dist. Thane -401 506

Respected Sir,

This is to submit to you that, the death of one person was reported at Saifee Hospital, Charnee road, Mumbai due to suspected ADR of the subjected drug. The distribution details of subjected drugs is collected from M/s Emcure Pharmaceuticals Ltd, Pune, same is attached herewith for your reference. You are requested to stop the use of said drug in your jurisdiction & ask to recall the stock from market.

Kindly treat the above matter on a top-priority basis.

Yours,

(S.B.Patil)

Joint Commissioner (Drugs) (Pune Division)
Food & Drugs Administration, M.S., Pune.

Copy submitted to -

Joint Commissioner, (Head Quarter) and Controlling Authority, Food and Drug Administration, MS for information.