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Page : 1 of 1
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FDA steps in to meet ever-rising demand for human albumin

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PUNE: The shortage of human albumin — a protein which helps maintain calcium levels and transports nutrients through bloodstream — in the state may end soon as the Maharashtra Food and Drug Administration (FDA) has stepped in to plug the demand-supply gap of the crucial drug by increasing its production at the Navi Mumbai-based Reliance Life Sciences.

Gujarat-based Intas and Reliance Life Sciences in Mumbai are the only two major companies in the country that manufacture the serum, which is desperately needed by patients suffering from liver diseases, kidney failure, burns or those who are malnourished. Doctors say the protein, which is naturally produced by a healthy liver, has been in short supply across the country for the last eight months or so.

"The shortage will be over by the end of this month. The FDA has helped the only manufacturer in the state, Reliance Life Sciences, to get requisite permissions from the Union government to double the production," state FDA commissioner Harshadeep Kamble told TOI on Thursday.

K V Subramaniam, president of Reliance Life Sciences, in his email reply to TOI confirmed the development.

The email stated: "The company has plans to increase its production from approximately 6 lakh litres of plasma per year to 10 lakh litres. It is difficult to know when the current product shortage will be resolved as it depends on the global demand- supply situation," Subramaniam said, adding, "The Reliance Life Sciences has received approvals for import of plasma for some territories, but it would need more approvals based on finalization of contracts. The company has requisite approvals for manufacturing albumin. We cannot comment on state-wise situation as the shortage of human albumin is a nation-wide problem."

Senior gastroenterologist and hepatologist Parimal Lawate said, "Certain liver conditions lead to kidney failure, which is called hepato-renal syndrome — a life-threatening condition. One of the mainstays of treatment to reverse this condition is administration of human albumin intravenously daily for five days as dialysis does not work in this condition. And this is precisely the situation when the shortage of human albumin badly affects the patients as there is no alternative."

Lawate added, "Awareness among doctors about using human albumin for specific conditions has considerably increased over the last two to four years. There has been a lot of data supporting its usage in patients of liver diseases including liver cirrhosis in particular."

Nephrologist Shrinivas Ambike said, "Human albumin is required only if the kidney donor and the recipient have different blood groups. It is prominently used in patients of liver diseases like cirrhosis and liver cell failure. A critically-ill patient, who is malnourished, also needs human albumin intravenously. It has been in short supply for more than eight months now."