## Pharmabiz





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## Only 45 blood banks provide plasma to produce human albumin in state

Shardul Nautiyal, Mumbai Monday, March 16, 2015, 08:00 Hrs [IST]

Even as there is acute shortage for human albumin, only 45 of the total 315 blood banks across the state are providing the vital blood component called plasma to manufacturers to produce albumin on a sustainable basis.

Ahmedabad-based Intas Pharmaceuticals and Mumbai-based Reliance Life Sciences are the only two manufacturers producing albumin through their own facilities currently, according to sources. It has also been learnt that only 60,000 litres of plasma is being supplied annually with each unit of plasma costing ₹400 as per prescribed guidelines.

An official from one of Mumbai's leading blood bank said,"The problem can be addressed in its entirety if the concept of component separation is implemented on ground as blood availability through voluntary donation is increasing but no serious effort is made to maximise the use of every unit of blood procured by blood banks. Blood need to be fractionated into packed cells or RBCs, platelets and plasma for its maximum utilisation.

Plasma separated from whole blood is also fractionated to produce many useful life-saving components such as Factor VIII, fibrinogen, albumin, and gamma globulin. India imports every year fractionated components valued at more than ₹50 crore.

Reliance Life Sciences is, however, also awaiting central government's approval on imports of plasma required for its production on a large scale. Official sources inform that Reliance is currently supplying human albumin under its brand Albu Rel to limited hospitals based on the demand.

According to stockists, human albumin is currently scarcely available with prices ranging between ₹3897 and ₹4092 respectively. Pharmaceutical companies like Bharat Serums and Baxter were among the major manufacturers, importers and suppliers of albumin in Indian markets. After slashing of prices by the NPPA, they have stopped supply to domestic markets.

Based on the market reports, NPPA chairman Injeti Srinivas has however clarified in an interview with Pharmabiz, "Albumin shortage is due to limited availability of human plasma and not related to price control. The present supply level is around one million vials per annum. Reliance Life Sciences is the major producer accounting for nearly 6 lakh vials per annum. Baxter supplies around 3 lakh vials, which are entirely imported from their principals. The rest account for around one lakh vials. The supply level has not significantly dipped in the past few months, but shortages may be due to supply-gap as compared to demand."

He further said that the NPPA had held elaborate discussions with the manufacturers and found that price is not the constraint. In fact, Reliance has expanded its capacity to one million vials per annum, but it is unable to produce at that level due to limited availability of raw material. Further, there are restrictions on import of human plasma due to safety concerns. Reliance Life Sciences have also stated in writing that the ceiling price for human albumin is not at all a constraint.

The price of one ml albumin injection of 20 per cent has been capped up to ₹36. 66 after being brought under Drug Price Control Order (DPCO) -2013 issued by the National Pharmaceutical Pricing Authority (NPPA). Albumin is an essential life-saving drug which should be priced reasonably, according to NPPA.

It has also been reported that human albumin low sodium of 20 per cent strength in 100 ml used to cost around ₹4,904 but was sold at a higher price of ₹5,980 due to the shortage following NPPA price cut. The emergency drug which is generally being used as a life saving drug in cases of severe blood loss or in trauma cases was earlier being imported by few companies in India.

Human albumin serum is a protein in human plasma of the blood which is produced in liver. It maintains levels of calcium in the body and transports nutrients or drugs effectively in the blood stream. The body can suffer a shortage of albumin if a patient is affected by liver disease, kidney failure, burns, malnourishment, etc. In kidney transplants, when the blood group of the donor and the recipient does not match, plasma content in the recipient's blood has to be drained and albumin has to be transfused so that the donated kidney may not be rejected.