

## » Ranbaxy Retail-Level Recall of Generic Atorvastatin

Ranbaxy has announced a retail/pharmacy level recall of multiple lots of atorvastatin, a generic version of Pfizer's Lipitor®. This voluntary recall is being issued because Ranbaxy discovered a quarter-sized piece of glass missing from one of its reactors. The inactive ingredient that was being processed in the reactor was inspected and tiny pieces of glass (<1 mm in size) were found in the batch. This inactive ingredient was pulled from production and never used in any finished medication. As a precautionary measure, Ranbaxy is recalling all medications that included an inactive ingredient that had previously been manufactured in the impacted reactor. Inspection of the recalled products have not shown evidence they contain any glass particles.

The recall includes several lots of Ranbaxy's atorvastatin 10mg, 20mg and 40mg tablets that were distributed between September 25, 2012 and October 26, 2012. It does not include the 80mg tablets.

This voluntary recall is only at the retail/pharmacy level. In this case, pharmacies are asked to check their stocks and stop dispensing product from the recalled lots. The FDA has not classified this as a patient level recall, and Ranbaxy, with approval from the FDA, has indicated patients may continue to take their atorvastatin. **As of Wednesday, Nov. 28 the FDA and the manufacturer of atorvastatin have determined based on the current evaluation, the probability of an adverse effect due to consumption of this product is remote.**

### Current Situation:

- Isolated shortages at retail pharmacies are occurring for some patients trying to fill atorvastatin.
- Our home delivery supply of atorvastatin remains sufficient.

### Current Action Being Taken:

- We are providing prior authorization overrides on an ad hoc basis to quantity level limit and step therapy programs impacting members obtaining fills at pharmacies experiencing shortages. The overrides allow a patient trying to fill atorvastatin to obtain brand Lipitor in cases where their pharmacy is unable to fill with generic.
- Until the supply issue is resolved, we will not apply the "members pay the difference" logic to brand Lipitor prescriptions.

- Atorvastatin and Lipitor will be removed from the legacy Medco Exclusive Home Delivery/RRA list on Dec. 5. This will ensure patients are not financially penalized by receiving a supply of these medications from any pharmacy should a shortage occur.

**Future Plans:**

- We are managing the situation to prevent any shortage from impacting our patients. Our procurement and pharmacy practice teams are developing mitigation strategies should a shortage occur.
- Multiple therapeutic alternatives to atorvastatin are available for managing high cholesterol. If patients are experiencing issues obtaining the drug, the role of the retail pharmacist is to discuss options with members and encourage them to speak to their doctor to obtain a prescription for an alternative medication, if necessary.

