AstraZeneca – Recall of Brilinta® (ticagrelor)

- On May 26, 2017, the FDA announced a voluntary, consumer-level recall of one lot of AstraZeneca's Brilinta (ticagrelor) 90 mg tablets, due to a report that a professional sample bottle containing eight tablets of Brilinta 90 mg also contained another medicine called Zurampic® (lesinurad) 200 mg tablets.
    - Other forms and dosage strengths of Brilinta, including medicine obtained via U.S. retail or mail order pharmacies, are not affected by this recall.
    - This recall does not affect Zurampic.
- The recalled lot was distributed to physicians between March and April 2017.

Product Description	NDC #	Lot # (Expiration Date)
Brilinta (ticagrelor) 90 mg tablets, 8-count professional physician sample bottles	00186-0777-08	JB5047 (10/2019)

- Brilinta is indicated to reduce the rate of cardiovascular death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel. Brilinta also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS.
- Brilinta carries a boxed warning for bleeding risk, aspirin dose and Brilinta effectiveness.
- Unintentional dosing with Zurampic has the potential to lead to adverse renal effects including acute renal failure which is more common when Zurampic is given alone, as it should be used in combination with a xanthine oxidase inhibitor.
- Brilinta has a warning in its prescribing information regarding discontinuation of the medicine. Missed doses of Brilinta increase the risk of heart attack and stroke. People who are treated with a stent and miss doses of Brilinta have a higher risk of getting a blood clot in the stent, having a heart attack, or death. Thus, patients should not stop taking Brilinta without talking to their prescribing doctor.
- Brilinta 90 mg tablets are supplied as a round, biconvex, yellow, film-coated tablet, and imprinted with 90 above a T on one side of the pill. Zurampic 200 mg tablets are blue in color and elliptical/oval in shape. They are imprinted with LES200 on one side of the pill.
- AstraZeneca is notifying physicians by recall letter and arranging for return of all recalled products. To date, AstraZeneca has not received any reports of adverse events related to this recall.

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- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.

- For questions regarding this recall, contact the AstraZeneca Information Center at **1-800-236-9933.**