

February 24, 2021

VOLUNTARY RECALL

**SERTRALINE (as Hydrochloride) [SERENATA] 50 mg Film-Coated Tablet
DRP-2698**

We, Torrent Pharma Philippines, Inc., is voluntary recalling (Recall Class III) up to Retail Level the below batch of:

GENERIC NAME:	SERTRALINE (AS HYDROCHLORIDE)
BRAND NAME:	SERENATA
DOASGE FORM AND STRENGTH:	50 MG FILM-COATED TABLET
REGISTRATION NUMBER:	DRP-2698
PACKAGING:	ALU/PVC/PVDC BLISTER PACK OF 10'S (BOX OF 30'S)
BATCH NUMBER:	BK36D002
MANUFACTURING DATE:	AUGUST 2017
EXPIRY DATE:	JULY 2021
MANUFACTURER:	TORRENT PHARMACEUTICALS LTD Indrad 382721 Dist. Mehsana, INDIA
IMPORTER / DISTRIBUTOR:	TORRENT PHARMA PHILIPPINES, INC. Units 3 & 4, 34th Floor Zuellig Building, Makati Avenue corner Paseo de Roxas, Makati City

The above product is subject for recall due to Out of Specification results in the Water Content Test at 36 months of Long-Term Stability Condition.

Sertraline (as hydrochloride) is used for the treatment of depression and any connected feeling of anxiety, obsessive-compulsive disorder, and for a female with post-traumatic stress disorder.

Sertraline (as Hydrochloride) [Serenata] 50 mg Film-Coated Tablets were distributed Nationwide. Torrent Pharma Philippines, Inc. is requesting concerned establishments (distributors, hospitals, pharmacies, and retailers, outlets) to discontinue further distribution, sale, and use. Consumers are likewise advised not to purchase or use the affected batch. You may contact Torrent Pharma Philippines, Inc. at (02)-8895-2097 or send an email to <http://www.torrentpharma.com/> for any questions regarding this recall.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph or through <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH>.