

July 01, 2022

VOLUNTARY RECALL

GLICLAZIDE 30 mg Prolonged Release Tablet DRP-3777 and DRP-3777-02

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

Product Description	Registration Number	Batch Number / Expiry Date	Packaging / Pack Size
Gliclazide 30 mg Prolonged-Release Tablet [Azukon MR]	DRP-3777	BU79G001 / 04-2022 BU79G002 / 04-2022 BU79G006 / 07-2022 BU79G007 / 07-2022 BU79G008 / 07-2022 BU79G009 / 07-2022 BU79G017 / 08-2022 BU79G018 / 08-2022 BU79G019 / 08-2022 BU79G020 / 08-2022 BU79G021 / 09-2022 BU79G022 / 09-2022 BU79H005 / 12-2022 BU79H006 / 12-2022 BU79H007 / 12-2022 BU79H009 / 02-2023 BU79H010 / 02-2023	Alu/PVC Blister Packs x 10's (Box of 100's)
Gliclazide 30 mg Prolonged-Release Tablet Marketing Authorization Holder [MAH]: TGP Pharma Inc.	DRP-3777-02	BU79G009 / 07-2022 BU79G019 / 08-2022 BU79H010 / 02-2023	Alu/PVC Blister Packs x 10's (Box of 100's)

The above products are subject for recall due to Out of Specification results in the Dissolution Test at Long-Term Stability Condition.

Gliclazide is used in the treatment of Type II Diabetes Mellitus.

Gliclazide 30 mg Prolonged-Release Tablets were distributed Nationwide. Torrent Pharma Philippines, Inc. is requesting concerned establishments (distributors, hospitals and retail pharmacies, and retailers, outlets) to discontinue further distribution, sale, and use of the above-mentioned batches. Consumers are likewise advised not to purchase or use the affected batches. 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>”.