OEP Philippines, Inc.

VOLUNTARY RECALL OF SPECIFIC BATCH OF ERDOSTEINE (ECTRIN) 300 MG CAPSULE

OEP Philippines, Inc. has initiated voluntary recall of a specific batch of Erdosteine 300 mg Capsule in response to report of out-of-specification dissolution test results received from the manufacturer, Orient Pharma Co., Ltd. with the following details:

DRUG PRODUCT	**ERDOSTEINE 300 mg CAPSULE [ECTRIN]**		
REGISTRATION NO.	**DR-XY29596**		
BATCH NO./MFG. DATE/ EXP. DATE	**E031185**	**02/2022**	**01/2025**
QUANTITY	1,155 Boxes x 100's		
MANUFACTURER	Orient Pharma Co., Ltd. No. 8 Kehu 1st Road, Huwei Township, Yunlin County 63247, Taiwan, R.O.C.		
UNDER LICENSE FROM	Edmond Pharma S.r.l. Via Dei Giovi, 131 Paderno Dugnano Milano, Italy		
IMPORTER	OEP Philippines, Inc. Unit 606, 6/F SEDCCO I Bldg ., cor. Rada & Legaspi Sts., Legaspi Village, Makati City		
DISTRIBUTOR	Zuellig Pharma Corporation Km. 14 West Service Road, South Super Hi-way cor. Edison Ave., Brgy. Sun Valley, Parañaque City		

Erdosteine capsule is indicated for the treatment of acute bronchitis, chronic bronchitis and its exacerbations, respiratory disorders characterized by abnormal bronchial secretions and impaired mucus transport.

This recall is isolated only to one specified batch number as mentioned in the table above.

Furthermore, no adverse events have been reported relating to this recall to date.

In the light of the foregoing, all healthcare professionals, establishments, and the general public are warned to discontinue further use, sale, and distribution of the specified batch of Erdosteine 300 mg Capsule.

Consumers may contact OEP Philippines, Inc. at telephone number +632 88151209 to 12 loc 1335 for any questions or additional information regarding the recall.

Any suspected adverse reaction experienced from the use of the pharmaceutical product but not limited to the batch number stated above should be reported immediately to FDA: www.fda.gov.ph or through: https://primaryreporting.who-umc.org/PH.