Recall Notice

VOLUNTARY DRUG RECALL

Product:	DIN:	Lot(s):
ACT RANITIDINE 150 mg tablets 60	02248570	K51136, K58444
ACT RANITIDINE 150 mg tablets 100	02248570	K50205, K50860, K51114, K51139, K51141, K52964, K58446
ACT RANITIDINE 150 mg tablets 500	02248570	K46486, K50593, K51071, K51076, K51144, K51146, K51148, K51150, K51152, K51154, K51164, K52965, K52966, K55591
ACT RANITIDINE 150 mg tablets P/P 60	02248570	K50203, K51069, K51132
ACT RANITIDINE 300 mg tablets 100	02248571	K50175, K50944, K51170, K51171, K51172, K51173

Distributed by:
Teva Canada Limited, Toronto, Canada

October 17, 2019

Dear Pharmacist(s):

Teva Canada Limited is voluntarily recalling **ACT RANITIDINE 150 mg and 300 mg tablets**, with the lot numbers noted above.

The voluntary recall is occurring due to the possible presence of an impurity N-nitrosodimethylamine (NDMA) – a probable human carcinogen in the Ranitidine active substance used in manufacturing the above finished product lots.

At present there is no evidence that this impurity has caused any harm to patients, however this recall action is being undertaken as a precautionary measure to prevent any further exposure to the impurity in the affected lots.

Teva Canada is proceeding with a **Type I** recall of the lot number noted above to the **Retail Level** with the knowledge of Health Canada.

Please examine your inventory and determine if you have any remaining stock with the lot numbers noted above. If you distributed product to another wholesaler, distribution center, retailer, please notify them to cease distribution.

If you ordered product direct from Teva Canada, you will be provided a recall package that includes a returns form. **Please return all products to your point of purchase.** Your account will receive a credit for all returns. If you have any specific questions regarding the recall process, please contact Teva Canada Customer Care at 1-800-268-4129.

Teva Canada would like to thank you for your understanding and continued support.

Teva Canada Limited