UPSHER-SMITH
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Contact: Elizabeth Likly
Kovak-Likly Communications
203-762-8833, elikly@klcpr.com

FOR IMMEDIATE RELEASE

UPSHER-SMITH RECEIVES FDA APPROVAL FOR BUMETANIDE TABLETS, USP

Bumetanide Tablets, USP
0.5 mg, 1 mg, and 2 mg
Upsher-Smith Laboratories, LLC

Maple Grove, MN – January 30, 2018 – Upsher-Smith Laboratories, LLC (Upsher-Smith) today announced that it has received U.S. Food and Drug Administration (FDA) approval of its abbreviated new drug application (ANDA) for Bumetanide Tablets, USP, 0.5 mg, 1 mg, and 2 mg. Bumetanide Tablets are a generic version of the brand product, Bumex® (bumetanide) Tablets.*

The bumetanide tablet market had U.S. sales of approximately $84.5 million for the 12 months ending November, 2017 according to IMS Health.

"Last year was an exciting one for Upsher-Smith," said Rusty Field, President and CEO of Upsher-Smith. "We were part of one of the largest pharmaceutical transactions of the year and continued to expand our generic product portfolio. We are pleased to begin this year by adding Bumetanide Tablets to our portfolio of quality generic products."

Product Information

Product	Strength	NDC #	Package Size
Bumetanide Tablets, USP	0.5 mg	0832-0540-11	100-ct Bottle
Bumetanide Tablets, USP	1 mg	0832-0541-11	100-ct Bottle
Bumetanide Tablets, USP	2 mg	0832-0542-11	100-ct Bottle

Upsher-Smith will be prepared to begin shipping product to wholesalers in early February 2018. For questions about ordering, please call Upsher-Smith at 1-800-654-2299.

WARNING

See full Prescribing Information for complete information.

Bumetanide is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required, and dose and dosage schedule have to be adjusted to the individual patient's needs (*see DOSAGE AND ADMINISTRATION*).

Please refer to the full Prescribing Information, including Boxed Warning for Bumetanide Tablets, USP at http://bit.ly/Bumetanide-Safety. You can also call 1-888-650-3789 to obtain a copy of the full Prescribing Information.

You are encouraged to report suspected adverse reactions to Upsher-Smith Laboratories, LLC at 1-855-899-9180 or to the FDA by visiting http://www.fda.gov/medwatch.

About Upsher-Smith

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that has strived to deliver quality, affordable generic medications for nearly a century. In June 2017, Upsher-Smith was acquired by Sawai Pharmaceutical Co., Ltd., a large publicly traded generics company in Japan that had been seeking entry into the U.S. market. Upsher-Smith and Sawai share a strikingly similar family history and hold many of the same cherished goals and values—most importantly, the philosophy of always putting patients first. Upsher-Smith will continue to do those things it does best, which is provide a consistent supply of quality, affordable medications and invest in its historically strong industry relationships. Ultimately, Upsher-Smith believes the acquisition by Sawai represents a tremendous opportunity to leverage each company for growth worldwide and embark together on an exciting new chapter in generics. For more information, visit www.upsher-smith.com.

* Bumex is a registered trademark of Validus Pharmaceuticals LLC.

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