

TARO PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 21, 2015

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE  
SECURITIES EXCHANGE ACT OF 1934

For the month of September, 2015

Commission File Number 001-35463

Taro Pharmaceutical Industries Ltd.

(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 2624761, Israel  
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes  No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):  
82-\_\_\_\_\_.

Taro Pharmaceutical Industries Ltd.  
c/o Taro Pharmaceuticals U.S.A., Inc.  
Three Skyline Drive  
Hawthorne, New York 10532  
(NYSE: TARO)

FOR IMMEDIATE RELEASE

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Taro's Keveyis™ (dichlorphenamide) 50 mg Tablets Now Available  
for the Treatment of Primary Hyperkalemic and Hypokalemic Periodic Paralysis

Hawthorne, NY, September 21, 2015 – Taro Pharmaceutical Industries Ltd. (NYSE: TARO) announced today that Keveyis™ (dichlorphenamide) 50 mg Tablets, the first medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of primary hyperkalemic and hypokalemic periodic paralysis and related variants, is now available for appropriate patients through its specialty pharmacy partner, Diplomat. Periodic paralysis is a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis.[1] It is estimated to affect approximately 5,000 people in the United States, up to 70 percent of which are currently undiagnosed.[2]

“Receiving an accurate diagnosis is a significant hurdle faced by many people living with this often debilitating disease,” said Kal Sundaram, Chief Executive Officer of Taro. “While it may take time to change the current environment, Taro is actively working towards building the disease awareness and understanding needed to make the path for people living with periodic paralysis an easier one.”

Beyond the introduction of Keveyis, Taro is committed to learning more about primary hyperkalemic and hypokalemic periodic paralysis through ongoing research and data publication. The Company is currently working with physician experts in an effort to create a patient registry, which it believes will lead to better understanding of the disease, its subtypes and the impact of Keveyis on different patients over time.

To ensure that people who may benefit from Keveyis can get access to the medicine as quickly as possible, and at an affordable price, Taro has also created the Keys2Care patient support program. Taro's goal is for patients to have little to no out-of-pocket cost. Through the program, people who are prescribed Keveyis are connected with a Diplomat representative who can assist them with navigating any required insurance approvals.

It may take several steps to gain access through an insurer. Here's how Keys2Care can support patients:

Keveyis will be provided to patients – at no cost – while insurance approvals are being investigated.

For those that do not have insurance, Keveyis will be provided – at no cost – while their Diplomat representative works to secure assistance for them.

For patients requiring additional financial assistance, Diplomat representatives will help to identify any co-pay assistance options and support provided through charitable foundations.

Finally, for those who qualify, through Taro's Patient Assistance program, Keveyis will be provided at no cost.

Keys2Care services can be accessed from 9 AM – 9 PM ET at 1-855-611-3401.

For more information about Keveyis go to [www.keveyis.com](http://www.keveyis.com).

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## About Periodic Paralysis

Periodic paralyses are a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Types of periodic paralyses are differentiated by criteria including underlying genetic mutations and changes in blood-potassium during attack. Hypokalemic and hyperkalemic are two common types of periodic paralyses.[1]

## INDICATION

Keveyis™ (dichlorphenamide) 50 mg tablets is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

## IMPORTANT SAFETY INFORMATION

In clinical studies, the most common side effects of Keveyis were a burning or pricking sensation, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects that you may experience with Keveyis. Talk to your doctor if you have any symptoms that bother you or do not go away.

Keveyis is not for everyone. Do not take Keveyis if you:

Are on a high-dose aspirin regimen

Are allergic to sulfa-based drugs

Have liver, kidney, or certain lung conditions

Are pregnant, planning to become pregnant, or nursing

It is not known whether Keveyis is safe or effective for people younger than 18 years of age. Taking Keveyis may cause a drop in the amount of potassium (an electrolyte) in your body, which can lead to heart problems. Ask your doctor if you need to eat foods that contain high amounts of potassium while taking Keveyis.

Your body may produce too much acid or may not be able to remove enough acid from body fluids while taking Keveyis. Your doctor may run tests on a regular basis to check for signs of acid buildup and may reduce your dose or stop your treatment with Keveyis.

Keveyis may also increase the risk of falls, especially in elderly patients and patients taking high doses of Keveyis. Use caution when driving, operating machinery, or performing any other hazardous activities while taking Keveyis, as this medication may cause drowsiness.

Tell your doctor if you experience worsening of your periodic paralysis symptoms.

For additional safety information, please see Full Prescribing Information at [www.keveyis.com](http://www.keveyis.com)

The release will be accessible on Taro's website at [www.taro.com](http://www.taro.com).

## About Taro

Taro Pharmaceutical Industries Ltd. is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality

healthcare products. For further information on Taro Pharmaceutical Industries Ltd., please visit the Company's website at [www.taro.com](http://www.taro.com).

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SAFE HARBOR STATEMENT

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements made by the Company's CEO and statements about the Company's Keys2Care and Patient Assistance programs in this press release. These statements include, but are not limited to, statements that do not describe historical facts or that refer or relate to events or circumstances that the Company "estimates," "believes," or "expects" to happen or similar language. Although the Company believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurances that its expectations will be attained. Factors that could cause actual results or events to differ include risks related to commercializing Keveyis, industry, market and regulatory conditions, delays or prevention caused by governmental regulation of pharmaceutical products, and other risks detailed from time to time in the Company's SEC reports, including its Annual Reports on Form 20-F. Forward-looking statements are applicable only as of the date on which they are made. The Company undertakes no obligations to update, change or revise any forward-looking statement, whether as a result of new information, additional or subsequent developments or otherwise.

[1] National Institute of Neurological Disorders and Stroke. NINDS Familial Periodic Paralysis Information Page. [http://www.ninds.nih.gov/disorders/periodic\\_paralysis/periodic\\_paralysis.htm](http://www.ninds.nih.gov/disorders/periodic_paralysis/periodic_paralysis.htm). National Institute of Neurological Disorders and Stroke. Published March 12, 2012. Accessed July 1, 2015.

[2] inVentiv Health, United Health Claims Database Analysis, October 2014.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 21, 2015

TARO PHARMACEUTICAL INDUSTRIES LTD.

By: /s/ Subramanian Kalyanasundaram

Name: Subramanian

Kalyanasundaram

Title: Chief Executive Officer  
and Director