

# **Teva Announces Availability of a Generic Equivalent of EpiPen Jr® (epinephrine injection, USP) Auto-Injector, 0.15 mg in the United States**

JERUSALEM & PARSIPPANY, N.J.--(BUSINESS WIRE)-- Teva Pharmaceutical Industries (NYSE and TASE: TEVA) today announced availability of the FDA-approved generic version of EpiPen Jr®<sup>1</sup> (epinephrine injection, USP) Auto-Injector, 0.15 mg, in the U.S. The product is available in most retail pharmacies, and the Wholesale Acquisition Cost is \$300<sup>2</sup> for a 2-pack.

”We’re pleased to provide access to Epinephrine Injection (Auto-Injector) in two strengths for patients who may experience life-threatening allergic emergencies,” said Brendan O’Grady, EVP and Head of North America Commercial. “We will continue working to ensure availability of both strengths in the US and plan to accelerate production to meet the urgent need for this medicine.”

With nearly 500 generic medicines available, Teva has the largest portfolio of FDA-approved generic products on the market and holds the leading position in first-to-file opportunities, with over 100 pending first-to-files in the US. Currently, one in nine generic prescriptions dispensed in the US is filled with a Teva product.

Teva’s generic equivalent of EpiPen® and EpiPen Jr® utilize the Antares Pharma (NASDAQ: ATRS) VIBEX® device. Antares and Teva have an exclusive License, Development and Supply Agreement for epinephrine auto injector products that Teva markets in the U.S.

## **About Epinephrine Injection**

Epinephrine Injection (Auto-Injector) is a prescription medicine in a disposable, prefilled automatic injection device (auto-injector) used to treat life-threatening, allergic emergencies including anaphylaxis in people who are at risk for or have a history of serious allergic emergencies. Each device contains a single dose of epinephrine.

Epinephrine Injection (Auto-Injector) is for immediate self (or caregiver) administration and does not take the place of emergency medical care. You should get emergency help right away after using Epinephrine Injection (Auto-Injector).

Epinephrine Injection, 0.3 mg (Auto-Injector) is for patients who weigh 66 pounds or more (30 kilograms or more). Epinephrine Injection, 0.15 mg (Auto-Injector) is for patients who weigh about 33 to 66 pounds (15 to 30 kilograms). It is not known if Epinephrine Injection (Auto-Injector) is safe and effective in children who weigh less than 33 pounds (15 kilograms).

## **IMPORTANT SAFETY INFORMATION**

Anaphylaxis can be life-threatening, can happen within minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or unknown causes. Use Epinephrine Injection (Auto-Injector) right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention. You may need to use a second Epinephrine Injection (Auto-Injector) if symptoms continue or recur. Only a healthcare provider should give additional doses of epinephrine if you need more than 2 injections for a single anaphylaxis episode.

Epinephrine Injection (Auto-Injector) should **only** be injected into the middle of your outer thigh (upper leg) through clothing if necessary. **Do not** inject the Epinephrine Injection (Auto-Injector) into your: veins, buttocks, fingers, toes, hands, or feet. If you inject a young child with Epinephrine Injection (Auto-Injector), hold their leg firmly in place before and during the injection to prevent injuries. If you accidentally inject Epinephrine Injection (Auto-Injector) into any other part of your body, go to the nearest emergency room right away. Tell the healthcare provider where on your body you received the accidental injection.

Rarely, patients who have used Epinephrine Injection (Auto-Injector) may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

**If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use your Epinephrine Injection (Auto-Injector).** Tell your healthcare provider about all known allergies, all your medical conditions and all the medicines you take, especially if you take asthma medicines.

Common side effects of Epinephrine Injection (Auto-Injector) include: fast, irregular or “pounding” heartbeat; sweating; headache; weakness; shakiness; paleness; feelings of over excitement, nervousness or anxiety; dizziness; nausea or vomiting; and breathing problems. These side effects may go away with rest. **Tell your healthcare provider if you have any side effect that bothers you or that does not go away.**

These are not all the possible side effects of Epinephrine Injection (Auto-Injector). For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information, please see accompanying [Full Prescribing Information](#).

A copy may be requested from Teva US Medical Information at 888-TEVA-USA (888-838-2872) or [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com), or Teva’s Public Relations or Investor Relations contacts.

## **About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people’s lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 3,500 products in nearly

every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at [www.tevapharm.com](http://www.tevapharm.com).

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding Teva's generic version of the EpiPen®, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to:

- the commercial success, including availability of sufficient supply, of Teva's generic version of the EpiPen® and EpiPen Jr®;
- our ability to successfully compete in the marketplace, including: that we are substantially dependent on our generic products; competition for our specialty products, especially COPAXONE®, our leading medicine, which faces competition from existing and potential additional generic versions and orally-administered alternatives; the uncertainty of commercial success of AJOVY® or AUSTEDO®; competition from companies with greater resources and capabilities; efforts of pharmaceutical companies to limit the use of generics, including through legislation and regulations; consolidation of our customer base and commercial alliances among our customers; the increase in the number of competitors targeting generic opportunities and seeking U.S. market exclusivity for generic versions of significant products; price erosion relating to our products, both from competing products and increased regulation; delays in launches of new products and our ability to achieve expected results from investments in our product pipeline; our ability to take advantage of high-value opportunities; the difficulty and expense of obtaining licenses to proprietary technologies; and the effectiveness of our patents and other measures to protect our intellectual property rights
- our substantial indebtedness, which may limit our ability to incur additional indebtedness, engage in additional transactions or make new investments, may result in a further downgrade of our credit ratings; and our inability to raise debt or borrow funds in amounts or on terms that are favorable to us;
- our business and operations in general, including: failure to effectively execute our restructuring plan announced in December 2017; uncertainties related to, and failure to achieve, the potential benefits and success of our senior management team and organizational structure; harm to our pipeline of future products due to the ongoing review of our R&D programs; our ability to develop and commercialize additional pharmaceutical products; potential additional adverse consequences following our resolution with the U.S. government of our FCPA investigation; compliance with sanctions and other trade control laws; manufacturing or quality control problems, which may damage our reputation for quality production and require costly remediation; interruptions in our supply chain; disruptions of our or third party information technology systems or breaches of our data security; the failure to recruit or retain key personnel; variations in intellectual property laws that may adversely affect our ability to

manufacture our products; challenges associated with conducting business globally, including adverse effects of political or economic instability, major hostilities or terrorism; significant sales to a limited number of customers in our U.S. market; our ability to successfully bid for suitable acquisition targets or licensing opportunities, or to consummate and integrate acquisitions; implementation of a new enterprise resource planning system that, if deficient, could materially and adversely affect our operations and/or the effectiveness of our internal controls; and our prospects and opportunities for growth if we sell assets;

- compliance, regulatory and litigation matters, including: costs and delays resulting from the extensive governmental regulation to which we are subject; the effects of reforms in healthcare regulation and reductions in pharmaceutical pricing, reimbursement and coverage; increased legal and regulatory action in connection with public concern over the abuse of opioid medications in the U.S.; governmental investigations into selling and marketing practices; potential liability for patent infringement; product liability claims; increased government scrutiny of our patent settlement agreements; failure to comply with complex Medicare and Medicaid reporting and payment obligations; and environmental risks;
- other financial and economic risks, including: our exposure to currency fluctuations and restrictions as well as credit risks; potential impairments of our intangible assets; potential significant increases in tax liabilities; and the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business;

and other factors discussed in our Quarterly Reports on Form 10-Q for the first and second quarter of 2019 and in our Annual Report on Form 10-K for the year ended December 31, 2018, including in the sections captioned "Risk Factors" and "Forward Looking Statements." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

<sup>1</sup> EpiPen® and EpiPen Jr® are registered trademarks of Mylan® Inc.

<sup>2</sup> Teva does not set the price that a pharmacy charges for a particular drug and does not have visibility or control into the price of the drug in the marketplace. View source version on [businesswire.com](https://www.businesswire.com/news/home/20190820005419/en/): <https://www.businesswire.com/news/home/20190820005419/en/>

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## **DISCLAIMER**

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