

The Medical Letter[®]

on Drugs and Therapeutics

Volume 62

October 19, 2020

ISSUE No.
1609

IN THIS ISSUE

Two New Doses of Dulaglutide (*Trulicity*) for Diabetesp 168

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Volume 62 (Issue 1609)

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▶ Two New Doses of Dulaglutide (*Trulicity*) for Diabetes

The FDA has approved two additional doses (3 mg and 4.5 mg) of the glucagon-like peptide-1 (GLP-1) receptor agonist dulaglutide (*Trulicity* – Lilly) for treatment of type 2 diabetes in adults. Dulaglutide has been available in 0.75- and 1.5-mg doses for years.¹

CLINICAL STUDIES – Approval of the two new doses was based on the results of a double-blind trial (AWARD-11; summarized in the package insert) that randomized 1842 patients with type 2 diabetes inadequately controlled on metformin monotherapy to receive dulaglutide 1.5, 3, or 4.5 mg SC once weekly. Reductions from baseline in A1C and weight at 36 weeks were statistically significantly greater with dulaglutide 4.5 mg (but not with 3 mg) than with the 1.5-mg dose.

1. Drugs for type 2 diabetes. Med Lett Drugs Ther 2019; 61:169.
2. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource[®] Monthly. October 5, 2020. Reprinted with permission by First Databank, Inc. All rights reserved. ©2020. www.fdbhealth.com/policies/drug-pricing-policy.

Table 1. Results of AWARD-11¹

Regimen	A1C Change (%) ²		Weight Change (kg) ²	
	36 wks ³	52 wks	36 wks	52 wks
Dulaglutide 1.5 mg once/wk (n=612)	-1.5	-1.6	-3.0	-3.5
Dulaglutide 3 mg once/wk (n=616)	-1.6	-1.7	-3.8	-4.3
Dulaglutide 4.5 mg once/wk (n=614)	-1.8 ⁴	-1.8 ⁴	-4.6 ⁴	-5.0 ⁴

1. According to the manufacturer.
2. Least-squares mean change from baseline.
3. The primary endpoint.
4. Statistically significant difference vs dulaglutide 1.5 mg.

ADVERSE EFFECTS – The most common adverse effects of dulaglutide in AWARD-11 were nausea, diarrhea, and vomiting; the incidences of these adverse effects were similar with all three doses.

DOSAGE AND COST – Dulaglutide is available in 0.75-, 1.5-, 3-, and 4.5-mg single-dose pens. The recommended starting dosage in the US is 0.75 mg SC once weekly. The weekly dose can be increased by 1.5 mg every 4 weeks as needed to a maximum of 4.5 mg. The 3- and 4.5-mg single-dose pens cost the same as the 0.75- and 1.5-mg pens. The cost of 4 weeks' treatment with dulaglutide is about \$800.² ■

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