PDL NEW DRUG REVIEW

Proprietary Name: Nesina®
Common Name: algoliptin
PDL Category: Diabetic - Other

Comparable Products	Preferred Drug List Status
Januvia	Preferred with Conditions
Onglyza	Preferred with Conditions
Tradjenta	Preferred with Conditions

Summary

Indications and Usage: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) in multiple clinical settings. Nesina® should not be used in patients with type 1 (DM) or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. This is a pregnancy category B medication. The safety and efficacy of use in children under the age of 18 have not been established.

Drug-Drug Interactions: There were no drug interactions noted.

Dosage Forms: Tablets: 6.25mg, 12.5mg, 25mg

Recommended Dosage: Take one table once daily, with or without food.

Dosage adjustment is not required in patients with mild renal impairment. The recommended dose is 12.5mg once daily for individuals with moderate renal impairment. The recommended dose is 6.25mg once daily for patients with severe renal impairment or end-stage renal disease. Due to the recommended dosage adjustments in patients with renal impairment, it is recommended that renal function be assessed prior to starting therapy and periodically thereafter.

Dosage adjustment is not required in individuals with mild to moderate hepatic impairment. Use has not been studied in patients with severe hepatic impairment. It is recommended that Nesina® be used with caution in patients with liver disease.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions = reported % incidence for drug minus reported % incidence for placebo.* The most common adverse events reported with Nesina® include nasopharyngitis (1.4%), headache (1.7%), and upper respiratory tract infection (2.1%). The incidence of hypoglycemia was 1.5% with the Nesina® group as compared with 1.6% in the placebo group.

Contraindications: Hypersensitivity to alogliptin or any component of the compound

Manufacturer: Takeda Pharmaceuticals America, Inc.

Analysis: Alogliptin, the active ingredient in Nesina, is a selective inhibitor of the enzymatic activity of dipeptidyl peptidase-4 (DPP-4). This inhibition slows the inactivation of the incretin hormones, resulting in an increase in incretin hormones and a reduction of fasting and postprandial glucose levels.

There were 3 randomized, double-blind studies to assess the efficacy of Nesina® when used in subjects having inadequate glycemic control on diet and exercise. In the first study (N=329), subjects were randomized to Nesina® or placebo for 26 weeks. Results suggested that there was a mean change from baseline in HbA1c of -0.6% with Nesina® vs 0% with placebo. Furthermore, 44% of the Nesina® group achieved an HbA1c ≤7% as compared with 23% of the placebo group (calculates to an NNT of 5). The change in body weight was comparable between treatments.

The second study (N=655) was an active-comparator trial that included Nesina® monotherapy vs pioglitazone 30mg monotherapy, Nesina® 12.5mg plus pioglitazone 30mg, and Nesina® 25mg plus pioglitazone 30mg. Results suggested that mean change from baseline in HbA1c was -1% with Nesina® 25mg vs -1.2% with pioglitazone, and -1.7% with Nesina® 25mg plus pioglitazone. The % achieving an HbA1c ≤7% was 24%, 34S%, and 63%, respectively. Mean increases in body weight were comparable between the pioglitazone and Nesina® plus pioglitazone combination.

The third study (N=784) was a double-blind, placebo-controlled study that compared placebo with metformin monotherapy (both 500mg and 1000mg BID), Nesina® monotherapy (12.5mg and 25mg BID) and with Nesina® in combination with metformin (Nesina® 12.5mg with both metformin 500mg and metformin 1000mg BID). Decreases in body weight were comparable between the metformin and the Nesina® plus metformin combination group. The Nesina combination group had statistically significant changes from baseline in HbA1c as compared with Nesina and metformin monotherapy groups. Differences from baseline in HbA1c were 0.1% with placebo, -0.6% with Nesina 12.5mg, -0.7% metformin 500mg, -1.1% with metformin 1000mg, -1.2% with Nesina® 12.5/metformin 500mg, and -1.6% with Nesina® 12.5/1000mg.

There is no evidence at this time to support that Nesina® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Nesina® remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Preferred with Conditions**
- ☐ **Preferred with Conditions**

References

[1] Nesina [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; 2013.