



# Summary of investigation results

## Alogliptin benzoate-containing drugs, Linagliptin, Teneligliptin hydrobromide hydrate

November 22, 2016

### Non-proprietary name

- (1) Alogliptin benzoate
- (2) Alogliptin benzoate/Pioglitazone hydrochloride
- (3) Linagliptin
- (4) Teneligliptin hydrobromide hydrate
- (5) Alogliptin benzoate/Metformin hydrochloride

### Brand name (Marketing authorization holder)

- (1) Nesina Tablets 6.25 mg, 12.5 mg, 25 mg (Takeda Pharmaceutical Co., Ltd.)
- (2) Liovel Combination Tablets LD & HD (Takeda Pharmaceutical Co., Ltd.)
- (3) Trazenta Tablets 5 mg (Nippon Boehringer Ingelheim Co., Ltd.)
- (4) Tenelia Tablets 20 mg (Mitsubishi Tanabe Pharma Corporation)
- (5) Inisync Combination Tablets (Takeda Pharmaceutical Co., Ltd.)

### Indications

- (1), (3), (4) Type 2 diabetes mellitus
- (2) Type 2 diabetes mellitus  
To be used only when the concomitant use of alogliptin benzoate and pioglitazone hydrochloride is considered appropriate
- (5) Type 2 diabetes mellitus  
To be used only when the concomitant use of alogliptin benzoate and metformin hydrochloride is considered appropriate

### Summary of revision

“Pemphigoid” should be newly added in the Clinically Significant Adverse Reactions.

### **Background of the revision and investigation results**

Cases of pemphigoid have been reported in patients treated with the above products in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

### **The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

The following cases associated with pemphigoid have been reported after administration of the following products:

(1) Alogliptin benzoate,

A total of 6 cases have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). One fatal case has been reported (including no fatal cases for which a causal relationship to the product could not be ruled out).

(2) Alogliptin benzoate/Pioglitazone hydrochloride

One case has been reported (including no cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

(3) Linagliptin

A total of 15 cases have been reported (including 10 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

(4) Teneligliptin hydrobromide hydrate

A total of 14 cases have been reported (including 7 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

(5) Alogliptin benzoate/Metformin hydrochloride

No cases have been reported.