

# Safety data sheet

## Prandin® 0.5 mg, Prandin® 1 mg, Prandin® 2 mg

### 1. Identification of the substance/preparation and of the company/undertaking

Prepared on: 25-01-2013/ FRSE

Distributor:

**Novo Nordisk A/S**  
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### 2. Hazards identification

The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.

#### Additional information

Prandin is an oral blood glucose-lowering drug of the meglitinide class used in the management of type 2 diabetes mellitus. Ingestion may result in a mild temporary decrease in the blood sugar level (hypoglycaemia). Prandin is rapidly eliminated from the blood stream with a half-life of approx. 1 hour.

### 3. Composition/information on ingredients

REACH registration number	CAS No./ EINECS no.	Substances	Classification/ CLP-classification	w/w%
-	135062-02-1	Oral anti-diabetic tablet contains 0,5-2 mg of S(+)-2-ethoxy-4-(2-oxo-2-((alpha-isobutyl-2-piperidinobenzyl)amino)ethyl)benzoic acid (Repaglinide)	Not classified	-

*Please see section 16 for the full text of R-phrases and H-phrases.*

### 4. First aid measures

#### Inhalation

Seek fresh air. Seek medical advice in case of persistent discomfort.

#### Ingestion

Rinse mouth thoroughly and then drink plenty of water. Do not induce vomiting. Seek medical advice in case of persistent discomfort.

#### Skin

Remove contaminated clothes immediately. Wash skin with soap and water. Seek medical advice in case of persistent discomfort.

#### Eyes

Flush immediately with water (preferably using eye wash equipment) for at least 5 minutes. Open eye wide. Remove any contact lenses. Seek medical advice.

#### Other information

When obtaining medical advice, show the safety data sheet or label.

### 5. Fire-fighting measures

Remove containers from the danger area if this is possible without risk. Extinguish with powder, foam, carbon dioxide or water mist. Do not inhale vapours and flue gases - seek fresh air.

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### 6. Accidental release measures

Use the same personal protection as for item 8. Sweep/pick up spill and place in suitable waste containers. For information on disposal please see item 13

### 7. Handling and storage

#### Handling

Please see item 8 for information on personal protection.

#### Storage

Prandin must be kept in tightly closed original packings in order to protect from moisture. Do not store above 25° C (77 ° F).

### 8. Exposure controls/ personal protection

#### Precautions for use

Work must be done with effective mechanical ventilation (e.g. local extractor fan). There must be access to running water and eye wash.

#### Respiratory protection

Not required.

#### Gloves and protective clothing

Wear disposable gloves made of PVC or nitrile rubber (NBR).

#### Eye protection

Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a risk of splashing.

#### Occupational exposure limits

Contains no substances subject to reporting requirements.

### 9. Physical and chemical properties

#### Appearance:

0,5 mg tablet (white)

1 mg tablet (yellow)

2 mg tablet (pink)

Molecular weight:452,6 Dalton

Chemical formula: C<sub>27</sub>H<sub>36</sub>N<sub>2</sub>O<sub>4</sub>

### 10. Stability and reactivity

The product is stable when used in accordance with the supplier's directions.

## 11. Toxicological information

### **Acute**

#### **Inhalation**

Inhalation of dust may cause irritation to the upper airways.

#### **Ingestion**

Ingestion may result in a mild temporary decrease in the blood sugar level (hypoglycaemia). Gastrointestinal disorders such as abdominal pain, diarrhoea.

#### **Skin contact**

Not investigated. May cause irritation. Avoid contact with the skin.

#### **Eye contact**

Not investigated. May cause irritation. Avoid contact with the eyes.

#### **Risk of sensitization**

Hypersensitivity and allergic reactions (e.g. anaphylactic reactions) to repaglinide or to any of the excipients.

#### **Long-term effects**

#### **May cause genetic damage**

Repaglinide did not show any genotoxic potential in the Ames test

#### **May cause irreversible damages**

Repeated dose studies in animals did not identify any target organ toxicity

## 12. Ecological information

Avoid discharge to drain or surface water.

## 13. Disposal considerations

The product is not hazardous waste.

It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications.

Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## 14. Transport information

The product is not covered by the rules for transport of dangerous goods by road and sea according to ADR and IMDG.

## 15. Regulatory information

**Hazard designation:** It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

#### **Contains**

Oral anti-diabetic tablet contains 0,5-2 mg of, S(+)-2-ethoxy-4-(2-oxo-2-((alpha-isobutyl-2-piperidinobenzyl)amino)ethyl)benzoic acid., (Repaglinide)

#### **Supplemental information**

None.

#### **Chemical safety assessment**

## 16. Other information

### Restrictions on use

None.

### Training requirement

No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

### Sources used

### Other information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

### Full text of the R-phrases that are stated in section 3.

No R-phrases.

### Full text of the H-phrases that are stated in section 3.

No H-phrases.