

PrandiMet® Tablets (Repaglinide 1 or 2 mg/Metformin 500 mg)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 1/23/2015

Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : PrandiMet® Tablets (Repaglinide 1 or 2 mg/Metformin 500 mg)

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Drug Product

1.3. Details of the supplier of the safety data sheet

Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
T 800-727-6500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number : 800-727-6500

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Eye Irrit. 2B H320
Resp. Sens. 1 H334
Lact. H362

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



GHS08

Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H320 - Causes eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H362 - May cause harm to breast-fed children

Precautionary statements (GHS-US)

: P201 - Obtain special instructions before use
P260 - Do not breathe dust
P261 - Avoid breathing dust
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P284 - [In case of inadequate ventilation] wear respiratory protection
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 - IF exposed or concerned: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P342+P311 - If experiencing respiratory symptoms: Call a Poison Center
P501 - Dispose of contents/container to comply with local/regional/national/international regulations

2.3. Other hazards

Other hazards not contributing to the classification

: This product contains the following inactive ingredients: poloxamer 188, microcrystalline cellulose, polacrillin potassium, magnesium stearate, hypromellose 3cp or 6cp, povidone, meglumine, sorbitol, talc, titanium dioxide, red or yellow iron oxide, and polyethylene glycol.

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Propylene glycol is present in the 2 mg/500 mg PrandiMet® tablets.

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Metformin hydrochloride (500 mg)	(CAS No) 1115-70-4	40	Acute Tox. 4 (Oral), H302 Eye Irrit. 2B, H320
Repaglinide	(CAS No) 135062-02-1	0.15 - 0.32	Resp. Sens. 1, H334 Lact., H362

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
First-aid measures after inhalation	: Not an anticipated route of entry. If inhaled, remove person to fresh air.
First-aid measures after skin contact	: Exposure not anticipated. Promptly wash with plenty of soap and water.
First-aid measures after eye contact	: Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get Immediate Medical Attention. Not likely unless the tablets are crushed. If you get dust in the eyes, rinse immediately with water (preferably using eye wash) for at least 15 minutes. Open eyes wide. Remove any contact lenses.
First-aid measures after ingestion	: Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: None under normal use. Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.
Symptoms/injuries after skin contact	: Not likely unless the tablets are crushed. May then cause slight irritation.
Symptoms/injuries after eye contact	: Not likely unless the tablets are crushed. May then cause temporary irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed. May cause hypoglycemia. Gastrointestinal reactions (e.g. diarrhea, nausea, vomiting) are the most common adverse reactions (> 5%) with metformin HCl treatment and are more frequent at higher metformin HCl doses.
Chronic symptoms	: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with PrandiMet®.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Any. Use media appropriate for surrounding fire.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: The product is not readily flammable.
Reactivity	: Not reactive under normal use and conditions.

5.3. Advice for firefighters

Protection during firefighting	: Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Do not inhale vapors and flue gases - seek fresh air.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

6.2. Environmental precautions

Under normal use, this product is not expected to impact the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Do not touch or walk through spilled material.

Methods for cleaning up : Absorb with non-combustible material and transfer to containers.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.

Hygiene measures : Do not eat, drink or smoke when using this product. Practice good housekeeping. Wash thoroughly after handling. Change contaminated clothing. Do not reuse until laundered.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Protect from moisture. Keep bottles tightly closed. Dispense in tight containers with safety closures.

Storage temperature : Do not store above 25° C (77° F).

7.3. Specific end use(s)

Drug Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Hand protection : Polyvinylchloride (PVC) / Nitrile rubber gloves.

Eye protection : Chemical goggles or safety glasses.

Skin and body protection : Nitrile rubber or similar protection are recommended for waste clear-up and manufacturing operations.

Respiratory protection : Not normally required. But if the tablets crushed and dust is released personal protection (breathing protection (filter type P2) must be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Biconvex pill.

Molecular mass : 165.63 g/mol

Colour : 1 mg/500 mg (yellow) and 2 mg/500 mg (pink) strengths.

Odour : None established.

Odour threshold : No data available

pH : No data available

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : No data available

Solubility : No data available

Log Pow : No data available

Log Kow : No data available

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Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal use and conditions.

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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Additional information	May cause hypoglycemia. May cause lactic acidosis. The onset of lactic acidosis often is subtle, and accompanied only by nonspecific symptoms
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Metformin hydrochloride (500 mg) (1115-70-4)

LD50 oral rat	1000 mg/kg "Merck Index; an Encyclopedia of Chemicals, Drugs, and Biologicals", 11th ed., Rahway, NJ 07065, Merck & Co., Inc. 1989Vol. 11, Pg. 934, 1989.
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Skin corrosion/irritation	: Not classified pH: No data available
Serious eye damage/irritation	: Causes eye irritation pH: No data available
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Pregnancy category C
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: None under normal use. Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.
Symptoms/injuries after skin contact	: Not likely unless the tablets are crushed. May then cause slight irritation.
Symptoms/injuries after eye contact	: Not likely unless the tablets are crushed. May then cause temporary irritation.

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Symptoms/injuries after ingestion	: Harmful if swallowed. May cause hypoglycemia. Gastrointestinal reactions (e.g., diarrhea, nausea, vomiting) are the most common adverse reactions (> 5%) with metformin HCl treatment and are more frequent at higher metformin HCl doses.
Chronic symptoms	: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with PrandiMet®.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations	: The product is not hazardous waste. Dispose in a safe manner in accordance with local/national regulations.
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SECTION 14: Transport information

In accordance with DOT

Not regulated for transport

Additional information

Other information	: No supplementary information available.
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ADR

Transport document description

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Metformin hydrochloride (500 mg) (1115-70-4)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Repaglinide (1-2mg) (135062-02-1)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

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15.2.2. National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources

- U.S. National Library of Medicine: DAILY MED
[<http://dailymed.nlm.nih.gov/dailymed/index.cfm>].
PrandiMet® Prescribing information.
Metformin. Catalog No. 1396309 [Online]. U. S. Pharmacopeia. Rockville, MD. November 20, 2012. www.usp.org
- Repaglinide*. Catalog No. 1600813 [Online]. U. S. Pharmacopeia. Rockville, MD. November 16, 2009. www.usp.org

Training advice

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

Full text of H-phrases: see section 16:

Lact.	Reproductive toxicity (Lact.)
Resp. Sens. 1	Respiratory sensitisation Category 1
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H362	May cause harm to breast-fed children

NFPA health hazard

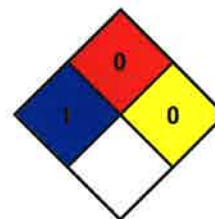
- 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

- 0 - Materials that will not burn.

NFPA reactivity

- 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product