

Safety data sheet

PrandiMet® Tablets

(Repaglinide 1 mg/Metformin 500 mg and 2 mg/Metformin 500 mg)

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

Product use: Tablets	Supplier: Novo Nordisk A/S, Miljøafdelingen Saantesvej 13 2820 Gentofte Tel:44 44 88 88 Fax: Contact person:Bente Jørgensen
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2. Hazards identification

Harmful if swallowed. Irritating to eyes and skin.
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3. Composition/information on ingredients

Einecs no.	CAS No.	Substances	Classification	w/w%
214-230-6	1115-70-4	Metformin hydrochloride	Xn;R22 Xi;R36/38	40
-	135062-02-1	Repaglinide 1mg, 2mg	Xn;R63, R64	0.15 (0.32)

Please see section 16 for the full text of the R-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. Seek medical advice in case of persistent discomfort.
Skin Remove contaminated clothing. Wash skin with soap and water.
Eyes 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 5 minutes. Open eyes wide. Remove any contact lenses.
Other information When obtaining medical advice, show the safety data sheet or label.

5. Fire-fighting measures

The product is not directly flammable. Avoid inhalation of vapour 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
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7. Handling and storage

Handling Please see item 8 for information on personal protection.
Storage Store at +15° C to 25° C Max. 60% humidity RH.

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8. Exposure controls/ personal protection

Precautions for use There must be access to running water and eye wash.					
Respiratory protection Not required.					
Gloves and protective clothing Disposable gloves of type PVC are recommended.					
Eye protection Not required.					
Occupational exposure limits					
Ingredients	Exposure limit	Remarks			
<table border="1"> <tr> <td colspan="3">Control methods Compliance with occupational exposure limits may be checked by occupational hygiene measurements</td> </tr> </table>			Control methods Compliance with occupational exposure limits may be checked by occupational hygiene measurements		
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9. Physical and chemical properties

Appearance: Tablets	Specific gravity or relative density:
Odor:	Solubility:
Odor threshold:	pH:
Physical state:	Melting/freezing point:

10. Stability and reactivity

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

11. Toxicological information

Acute
Inhalation Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.
Ingestion Harmful if swallowed.
Skin contact Not likely unless the tablets are crushed. May then cause slight irritation.
Eye contact Not likely unless the tablets are crushed. May then cause temporary irritation.
Long-term effects None known.

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12. Ecological information

Avoid discharge to drain or surface water.

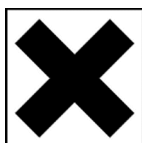
13. Disposal considerations

Collect spills and waste in closed and sealed containers and send to the local disposal facility for chemical waste.

14. Transport information

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

15. Regulatory information



Harmful

Hazard designation: Harmful

Hazard symbols: Xn

Contains

Repaglinide 1 mg, 2 mg, Metformin hydrochloride 500 mg

R-phrases

Harmful if swallowed (R22)
Irritating to eyes and skin (R36/38)

S-phrases

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice (S26)
Wear suitable protective clothing (S36)
(S36)

Other labelling

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

The Chemicals (Hazard Information and Packaging for Supply) Regulations
The list of dangerous substances

Other information

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

R22 Harmful if swallowed
R36/38 Irritating to eyes and skin
R63 Possible risk of harm to the unborn child
R64 May cause harm to breast-fed babies