



Apgar score after: 1 min:   5 min:   10 min:

Were any malformations, anomalies diagnosed in the newborn infant? Yes \* No   
 \*Please provide details on AE page and report in the timeframe for SAEs

Any other health problems in the newborn infant? Yes \* No   
 \*Please provide details on AE page and consider if the event classifies for SAE reporting

**Development after birth**

**Follow-up information on the infant** (preferably at 4-6 weeks of age)

Age at follow-up:   weeks Healthy baby? Yes  No \*  
 \*Please provide details on AE page and consider if the event classifies for SAE reporting

Is/was the mother taking NN product(s) while breastfeeding? Yes  No

**Additional maternal information**

**Maternal risk factors (e.g. medical conditions including diabetes complications, abuse, current or past medical treatment including chemotherapy, age, occupation, inborn disease in family, consanguinity i.e. family relationship by blood)**

Risk factor/medical history	Onset date	Stop date	Ongoing
	<input type="text"/> D D M M M Y Y Y Y	<input type="text"/> D D M M M Y Y Y Y	Yes <input type="checkbox"/> No <input type="checkbox"/>
	<input type="text"/> D D M M M Y Y Y Y	<input type="text"/> D D M M M Y Y Y Y	Yes <input type="checkbox"/> No <input type="checkbox"/>
	<input type="text"/> D D M M M Y Y Y Y	<input type="text"/> D D M M M Y Y Y Y	Yes <input type="checkbox"/> No <input type="checkbox"/>

Course of chronic disease during pregnancy (e.g. HbA1C)  
 \_\_\_\_\_

**Obstetric history**

Number of previous pregnancies:  If 0, proceed to "Paternal Information"

Outcome of previous pregnancies:

Live birth? Yes  No  If Yes, how many? :

Foetal death? Yes  No  If Yes, how many? :

Any congenital anomalies? Yes  No  If yes, specify \_\_\_\_\_

Termination of Pregnancy? Yes  No  If yes, specify the reason \_\_\_\_\_

Any other previous maternal pregnancy complications?  
 \_\_\_\_\_

**NN internal use only** Local ref. no/ GCC case no IPS case no

Initial Receipt Date and initials IPS Receipt date and initials

**Pregnancy Form for Marketed Products – Form B**  
 (for pregnancy with complications and/or abnormal pregnancy outcome)

Document no: 054725  
 Edition: 16.0  
 Enclosure 4  
 Page 3 of 6

<b>Current pregnancy</b>																																														
Date of last menstrual period (LMP):  <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> </tr> <tr> <td style="text-align: center;">D</td><td style="text-align: center;">D</td><td style="text-align: center;">M</td><td style="text-align: center;">M</td><td style="text-align: center;">M</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td> </tr> </table>											D	D	M	M	M	Y	Y	Y	Y	Y	Gestational age at time of reporting: weeks <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr></table> day(s) <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 15px;"></td><td style="border: 1px solid black; width: 20px; height: 15px;"></td></tr></table> Determined by LMP <input type="checkbox"/> or Ultrasound <input type="checkbox"/>					Expected delivery date:  <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> </tr> <tr> <td style="text-align: center;">D</td><td style="text-align: center;">D</td><td style="text-align: center;">M</td><td style="text-align: center;">M</td><td style="text-align: center;">M</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td><td style="text-align: center;">Y</td> </tr> </table>											D	D	M	M	M	Y	Y	Y	Y	Y
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Number of foetuses: 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>																																														

Any complications in the pregnancy? Yes \* No   
 \*Please provide event details on AE page and consider if the event(s) classifies for SAE reporting

**Serology**  
 Any infections during the pregnancy with: Toxoplasmosis  Rubella  Cytomegalovirus   
 Parvovirus  Other  If Other, specify: \_\_\_\_\_

Any fertility therapy prior to pregnancy? Yes  No  If Yes, specify  
 \_\_\_\_\_

**Relevant tests and laboratory data/vital signs** (e.g. HbA1C, liver enzymes, BP, albuminuria, foetal investigations)

Date performed	Test	Result	Units	Reference range																				
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Exposure to Novo Nordisk product(s) <i>Maternal exposure</i> <input type="checkbox"/> <i>Paternal exposure</i> <input type="checkbox"/>	Total daily dose at time of pregnancy (incl. units)	Route	Treatment start date	If discontinued, stop date																																								
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