

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

This form must be returned to the MAH who provided the product. Please see contact details below:

NOTE: Please use the first three letters of the month (e.g.: JAN)

Reporter information		
Reporter Name:		
Address:		
City, County, Country:		
Phone No.:		
Fax No.:		
Patient information		
Patient ID: Date of Birth: D M O N Y Y Y Ethnicity:		
Partner of patient information		
○ Not applicable		Ethnicity:
Pregnancy outcome		
Date of delivery: D D M	ΟΝΥΥΥ	Gestation age at delivery:
Normal	○ No ○ Yes	
C-section	○ No ○ Yes	
Induced	○ No ○ Yes	
Ectopic pregnancy	○ No ○ Yes	
Elective termination	\bigcirc No \bigcirc Yes	Date: D D M O N Y Y Y
Spontaneous abortion (≤20 weel	ks) \bigcirc No \bigcirc Yes	Weeks from LMP:
Foetal death/stillbirth (>20 weeks)	○ No ○ Yes	
Were the products of conception	○ No ○ Yes	If yes, was the foetus normal? O No O Yes O Unknown If no, describe belo
examined?		
Obstetrics information		
Complications during pregnancy	◯ No ◯ Yes	If yes, please specify
Complications during labour/delivery	○ _{No} ○ _{Yes}	If yes, please specify
Post-partum maternal complications	○ _{No} ○ _{Yes}	If yes, please specify
Foetal outcome		
Live normal infant	\bigcirc No \bigcirc Yes	
Foetal distress	○ No ○ Yes	
Intra-uterine growth retardation	○ No ○ Yes	
Neonatal complication	○ No ○ Yes	If yes, please specify
Birth defect noted?	○ No ○ Yes	If yes, please specify
Sex: O Male O Female Birth weight: lbs oz. or kg Length: inches or cm.		
Apgar score: 1 min: 5 min: 10 min: O Unknown		
Signature of person completing this form		
Signature:		
		Date: D D M O N Y Y Y

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Drug Safety Data Privacy notice

Your personal data will be processed by the relevant marketing authorisation holder, and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes. Should you have any queries in relation to the use of your personal data please contact the relevant marketing authorisation holder.

Description <thDescription</th> <thDescription</th>

Thank you for providing information that will assist us in our commitment to patient safety.