

Version 01

Effective Date: 2<sup>nd</sup> of April 2026

**Event-Specific Questionnaire for HCP – Pregnancy Outcome Form**

**This form must be returned to Adalvo Ltd:**



Email: [pharmacovigilance@adalvo.com.mt](mailto:pharmacovigilance@adalvo.com.mt)

**Approved by the Malta Medicines Authority on the 2<sup>nd</sup> of April 2026.**

**Reporting of Adverse Reactions**

**Suspected adverse reactions and medication errors should be reported either to:**

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,  
Sir Temi Zammit Buildings, Malta Life Sciences Park,  
San Gwann SGN 3000, Malta  
Website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)  
e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

or

Adalvo Limited  
Malta Life Sciences Park,  
Sir Temi Zammit,  
Building 1, Level 4,  
San Gwann Industrial Estate,  
San Gwann, SGN 3000,  
Malta  
Email: [pharmacovigilance@adalvo.com](mailto:pharmacovigilance@adalvo.com)  
Tel: +0040 727251514

**Event-Specific Questionnaire for HCP – Pregnancy Outcome Form****This form must be returned to Adalvo Ltd:**Email: [pharmacovigilance@adalvo.com.mt](mailto:pharmacovigilance@adalvo.com.mt)**NOTE:** Please use the first three letters of the month (e.g.: JAN)

<b>Reporter information</b>	
Reporter Name:	
Address:	
City, Country:	
Phone No.:	
Fax No.:	

<b>Patient information</b>	
Patient ID:	Date of Birth:
Ethnicity: <input type="checkbox"/> White <input type="checkbox"/> African-Caribbean <input type="checkbox"/> Other, specify:	

<b>Partner of patient information</b>
Not applicable <input type="checkbox"/> Ethnicity: <input type="checkbox"/> White <input type="checkbox"/> African-Caribbean <input type="checkbox"/> Other, specify:

<b>Pregnancy outcome</b>	
Date of delivery:	Gestation age at delivery:

Normal	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
C-section	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Induced	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Ectopic pregnancy	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Elective termination	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date:
Spontaneous abortion ( $\leq 20$ weeks)	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Weeks from LMP:
Foetal death/stillbirth ( $>20$ weeks)	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Were the products of conception examined?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, was the foetus normal? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown

If no, describe below:

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**Obstetrics information**

Complications during pregnancy	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, please specify	<input type="text"/>
Complications during labour/delivery	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, please specify	<input type="text"/>
Post-partum maternal complications	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, please specify	<input type="text"/>

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**Foetal outcome**

Live normal infant	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Foetal distress	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Intra-uterine growth retardation	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
Neonatal complication	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, please specify <input type="text"/>
Birth defect noted?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, please specify <input type="text"/>

Sex: Male Female      Birth weight: lbs.....oz. or..... kg      Length:..... inches .....or cm.  
 Apgar score: 1 min:.....5 min: .....10 min .....  Unknown

**Signature of person completing this form**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Drug Safety Data Privacy Notice**

Your personal data will be processed by Adalvo Ltd, for the purposes of complying with its drug safety legal obligations and for storage purposes.

Adalvo Ltd may share your data with other entities and third parties providing services to Adalvo Ltd. This may entail the transfer of your data to other countries. When such countries do not provide an equivalent level of protection to personal data as your country, Adalvo Ltd will implement appropriate legal, organisational, and technical security measures to protect your information from unauthorised access, use or disclosure, including the use of standard data protection clauses and Binding Corporate Rules. Adalvo Ltd will retain your personal data for the length of time required by law.

You have the right to access and verify your personal information held by Adalvo Ltd, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing.

For the exercise of your rights and for any questions regarding data protection you can contact Adalvo Ltd. If you are unhappy about how Adalvo Ltd is processing your personal data, you have the right to lodge a complaint with the supervisory authority.

**Reporter’s Signature (required):**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_