

Pomalidomide

**Pregnancy Report Form**

**Pregnancy reports for Pomalidomide must be sent to ADALVO LTD IMMEDIATELY**

This form must be returned to Adalvo Ltd

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

**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

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

**Patient Data**

Sex of Patient: Female    Male

- Pregnancy of Patient
- Pregnancy of Patient's Partner **OR**
- Exposure of a Pregnant Female (complete information below)

Exposure of a Pregnant Female (complete information below)

Pregnant Woman's Initials (F, M, L):				Date of Birth:	Age:
Patient Initials (F, M, L): (Who received drug)				Date of Birth:	Age:
Drug Name:					
Date of First Dose:			Date of Last Dose:		

Pregnancy Initially Diagnosed By:

- Home Urine Test
- Office Urine Test
- Serum Test

Date of Pregnancy Test: *DDMONYYYY*      Last Menstrual Period *DDMONYYYY*

Female is currently:  weeks pregnant **OR** No longer Pregnant    Unknown

Female has elected to:

Carry Pregnancy to Term, Expected Date of Delivery: *DDMONYYYY*

Terminate Pregnancy, Date Performed or Pending: *DDMONYYYY*

**Reporter's Information:**

Reporter's Name:		Date:	<i>DDMONYYYY</i>
Reporter's Contact Information/ Address:		Reporter's Signature:	
		Reporter's Phone Number:	
Reporter's Email Address:		Reporter's Fax Number:	

**Patient's Prescribing Physician's Information:**

Physician's Name:		Date:	<i>DDMONYYYY</i>
Physician's Contact Information/ Address:		Physician's Signature:	
		Physician's Phone Number:	
Physician's Email		Physician's Fax N	

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Address:		umber:	
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**Background Information on Reason for Pregnancy**

<b>Was patient erroneously considered not to be of childbearing potential?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<b>If yes, state reason for considering not to be of childbearing potential</b>		
<ul style="list-style-type: none"> <li>Age ≥ 50 years and naturally amenorrhoeic* for ≥1 year</li> <li>*amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Premature ovarian failure confirmed by a specialist gynaecologist</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Previous bilateral salpingo-oophorectomy, or hysterectomy</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>XY genotype, Turner syndrome, uterine agenesis.</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<b>Indicate from the list below what contraception was used</b>		
<ul style="list-style-type: none"> <li>Implant</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Levonorgestrel-releasing intrauterine system (IUS)</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Medroxyprogesterone acetate depot</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Tubal sterilisation (specify below)</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
Tubal ligation	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
Tubal diathermy,	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
Tubal chips	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Ovulation inhibitory progesterone-only pills (i.e. desogestrel)</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Other progesterone-only pills</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Combined oral contraceptive pill</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Other intra-uterine devices</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Condoms</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Cervical cap</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Sponge</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Withdrawal</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Other</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>None</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<b>Indicate from the list below the reason for contraceptive failure</b>		
<ul style="list-style-type: none"> <li>Missed oral contraception</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Other medication or intercurrent illness interacting with oral contraception</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Identified mishap with barrier method</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Unknown</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Had the patient committed to complete and continuous sexual abstinence</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Was the drug started despite patient already being pregnant?</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Did patient receive educational materials on the potential risk of teratogenicity?</li> </ul>	<input type="checkbox"/> Yes	<input type="checkbox"/> NO
<ul style="list-style-type: none"> <li>Did patient receive instructions on need to avoid pregnancy?</li> </ul>	Yes	NO

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**Background Information on Reason for Pregnancy**

**Prenatal information**

Date of Last Menstrual Period: *DDMONYYYY* ... Estimated Delivery Date: *DDMONYYYY* ...

**Pregnancy test**

Urine Qualitative <input type="checkbox"/>	Reference Range:		Date: : <i>DDMONYYYY</i>
Serum Quantitative <input type="checkbox"/>	Reference Range:		Date: : <i>DDMONYYYY</i>

**Past Obstetric History**

Year of Pregnancy Outcome					Gestationa l Age	Type of Delivery
<i>YYYY</i>	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
<i>YYYY</i>	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
<i>YYYY</i>	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
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<i>YYYY</i>	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		
<i>YYYY</i>	<input type="checkbox"/> Spontaneous abortion	<input type="checkbox"/> Therapeutic abortion	<input type="checkbox"/> Live birth	<input type="checkbox"/> Still birth		

**Birth defects**

Was there any birth defect from any pregnancy?  Yes  No  Unknown

Is there any family history of any congenital abnormality abstinence?  Yes  No  Unknown

**If yes to either of these questions, please provide details below:**

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**Maternal Past Medical History**

Condition	Dates	Treatment	Outcome
	From: <i>DDMMYYYY</i> To: <i>DDMMYYYY</i>		
	From: <i>DDMMYYYY</i> To: <i>DDMMYYYY</i>		
	From: <i>DDMMYYYY</i> To: <i>DDMMYYYY</i>		
	From: <i>DDMMYYYY</i> To: <i>DDMMYYYY</i>		

**Maternal Current Medical Conditions**

Condition	From	Treatment
	<i>DDMMYYYY</i>	
	<i>DDMMYYYY</i>	
	<i>DDMMYYYY</i>	
	<i>DDMMYYYY</i>	

**Maternal Social History**

Alcohol  Yes  No  
 If yes, amount/units per day:

Tobacco  Yes  No  
 If yes, amount per day:

IV or recreational drug use  Yes  No  
 If yes, provide details:

**Maternal medication during pregnancy and in 4 weeks before pregnancy**

(including herbal, alternative and over the counter medicines and dietary supplements)

Medication/treatment	Dates	Indication
	Start Date: <i>DDMMYYYY</i> Stop Date/ Continuing: <i>DDMMYYYY</i>	
	Start Date: <i>DDMMYYYY</i> Stop Date/ Continuing: <i>DDMMYYYY</i>	
	Start Date: <i>DDMMYYYY</i> Stop Date/ Continuing: <i>DDMMYYYY</i>	
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**Name of person completing this form**

Name:

Signature:

Date:

**Data Privacy Notice**

Your personal data will be processed by Adalvo Ltd as marketing authorisation holder of pharmaceutical products 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.

To conduct risk management programme activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

Adalvo Ltd may disclose your personal information to regulatory authorities, affiliates, service providers or other collaborators. Some of these entities may be located outside of the EU. Adalvo Ltd will take appropriate measures, such as implementing standard data protection clauses, to ensure that your personal information will be kept secure in accordance with applicable data protection law. Adalvo Ltd will only retain your personal data for the length of time required by law.

Under applicable law, you may 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

**Reporter's Signature (required):**

Signature:

Date: