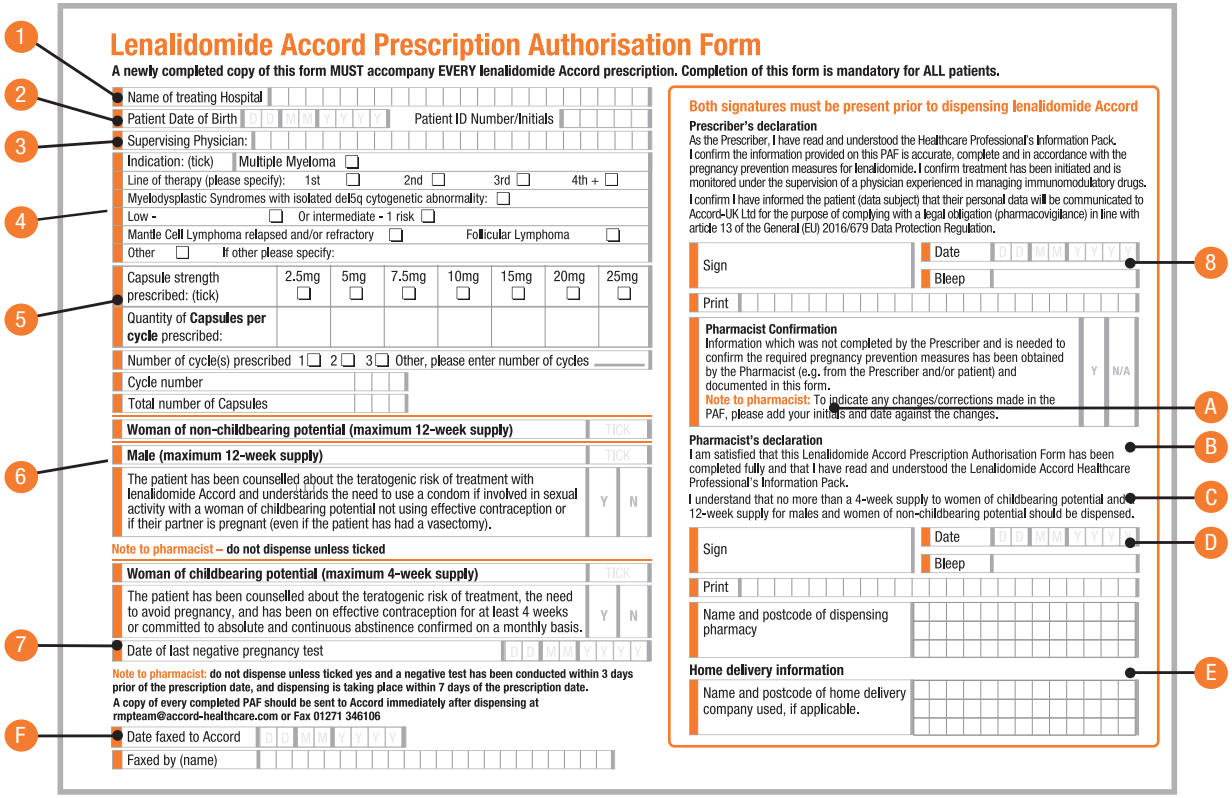
A guide to Completing the Prescription Authorisation Form (PAF)

The guide will help you complete the Lenalidomide Accord Prescription Authorisation form. The form is in the Healthcare Professional's Information Pack and must be completed each time you prescribe lenalidomide Accord for all patients.

A copy of the completed forms must be returned to Accord-UK Ltd, using the contact details below.



Lenalidomide Accord Prescription Authorisation Form

A newly completed copy of this form MUST accompany EVERY lenalidomide Accord prescription. Completion of this form is mandatory for ALL patients.

1 Name of treating Hospital

2 Patient Date of Birth (D D M M Y Y Y Y) Patient ID Number/Initials

3 Supervising Physician:

Indication: (tick) Multiple Myeloma ☐

Line of therapy (please specify): 1st ☐ 2nd ☐ 3rd ☐ 4th + ☐

Myelodysplastic Syndromes with isolated del5q cytogenetic abnormality: ☐

4 Low - ☐ Or intermediate - 1 risk ☐

Mantle Cell Lymphoma relapsed and/or refractory ☐ Follicular Lymphoma ☐

Other ☐ If other please specify:

5

Capsule strength prescribed: (tick)	2.5mg ☐	5mg ☐	7.5mg ☐	10mg ☐	15mg ☐	20mg ☐	25mg ☐
Quantity of **Capsules per cycle** prescribed:							

Number of cycle(s) prescribed 1 ☐ 2 ☐ 3 ☐ Other, please enter number of cycles

Cycle number

Total number of Capsules

6

	TICK	Y	N
Woman of non-childbearing potential (maximum 12-week supply)			
Male (maximum 12-week supply)			
The patient has been counselled about the teratogenic risk of treatment with lenalidomide Accord and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).			

Note to pharmacist – **do not dispense unless ticked**

	TICK	Y	N
Woman of childbearing potential (maximum 4-week supply)			
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been on effective contraception for at least 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.			

7 Date of last negative pregnancy test (D D M M Y Y Y Y)

Note to pharmacist: **do not dispense unless ticked yes and a negative test has been conducted within 3 days prior of the prescription date, and dispensing is taking place within 7 days of the prescription date.**

A copy of every completed PAF should be sent to Accord immediately after dispensing at rmpteam@accord-healthcare.com or Fax 01271 346106

F Date faxed to Accord (D D M M Y Y Y Y)

Faxed by (name)

Both signatures must be present prior to dispensing lenalidomide Accord

Prescriber's declaration

As the Prescriber, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the pregnancy prevention measures for lenalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

I confirm I have informed the patient (data subject) that their personal data will be communicated to Accord-UK Ltd for the purpose of complying with a legal obligation (pharmacovigilance) in line with article 13 of the General (EU) 2016/679 Data Protection Regulation.

Sign — Date (D D M M Y Y Y Y) — 8

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Pharmacist Confirmation

Information which was not completed by the Prescriber and is needed to confirm the required pregnancy prevention measures has been obtained by the Pharmacist (e.g. from the Prescriber and/or patient) and documented in this form.

Note to pharmacist: To indicate any changes/corrections made in the PAF, please add your initials and date against the changes. — Y / N/A — A

Pharmacist's declaration

I am satisfied that this Lenalidomide Accord Prescription Authorisation Form has been completed fully and that I have read and understood the Lenalidomide Accord Healthcare Professional's Information Pack. — B

I understand that no more than a 4-week supply to women of childbearing potential and 12-week supply for males and women of non-childbearing potential should be dispensed. — C

Sign — Date (D D M M Y Y Y Y) — D

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Name and postcode of dispensing pharmacy

Home delivery information — E

Name and postcode of home delivery company used, if applicable.

MHRA approval date - 25/07/2022

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Instructions for prescribers

1. Print the full Hospital name where the patient is treated.
2. Print the patient's Date of Birth. Do not provide confidential information (e.g. Patient Name and Hospital Number).
3. Print name clearly of supervising physician i.e physician experienced in managing immunomodulatory drugs and supervising treatment.
4. Tick the diagnosis box or state other usage – this will allow an assessment of the clinical usage of lenalidomide Accord, which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Programme.
5. Enter the capsules strength and quantity of each strength prescribed.
6. Complete this section appropriately to indicate the counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention Programme.
7. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescribing). If this is not the case lenalidomide Accord must not be dispensed.
8. You must sign, date and print your name to declare that all steps have been observed and that you authorise the Prescription Authorisation Form.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber
   a. Counselling and contraception measures must be in place
   b. Prescription must be accompanied by a Prescription Authorisation Form
   c. For women of childbearing potential lenalidomide Accord can only be dispensed within 7 days of the prescription date.
   d. Only a maximum of 4 weeks supply for women of childbearing potential, or a maximum of 12 weeks supply for all other patients, of lenalidomide Accord can be dispensed at any one time

B. Check the form does not contain confidential information (e.g. Patient Name and Hospital Number) – Accord will not accept PAFs that do not maintain anonymity.

C. Check the form is complete and legible – Accord will request that **ALL** incomplete or illegible forms are resent. If you obtained information from the prescriber or patient to complete the form, please follow the instructions in the Pharmacist Confirmation box.

D. You must sign, date and print your name to declare that the form has been completed fully and dispensing for women of childbearing potential is taking place within 7 days of the date of prescription.

E. Complete the Home delivery information if applicable.

F. Complete the "Date faxed to Accord" and "Faxed by (Name)" fields and **FAX** completed forms to Accord on **01271 346106.**

Further information and materials are available from Accord.

Telephone: +44(0)7917920374
E-mail: rmpteam@accord-healthcare.com
Fax – 01271 346106
Address: FREEPOST RRBA-EEYZ-JYUX, Accord-UK Ltd,
Medical information department, Whiddon Valley, Barnstaple, EX32 8NS

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Cycle number

Total number of Capsules

Woman of non-childbearing potential (maximum 12-week supply) TICK

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	Y	N
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	Y	N
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Date of last negative pregnancy test D D M M Y Y Y Y

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Name and postcode of dispensing pharmacy

Home delivery information

Name and postcode of home delivery company used, if applicable.

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