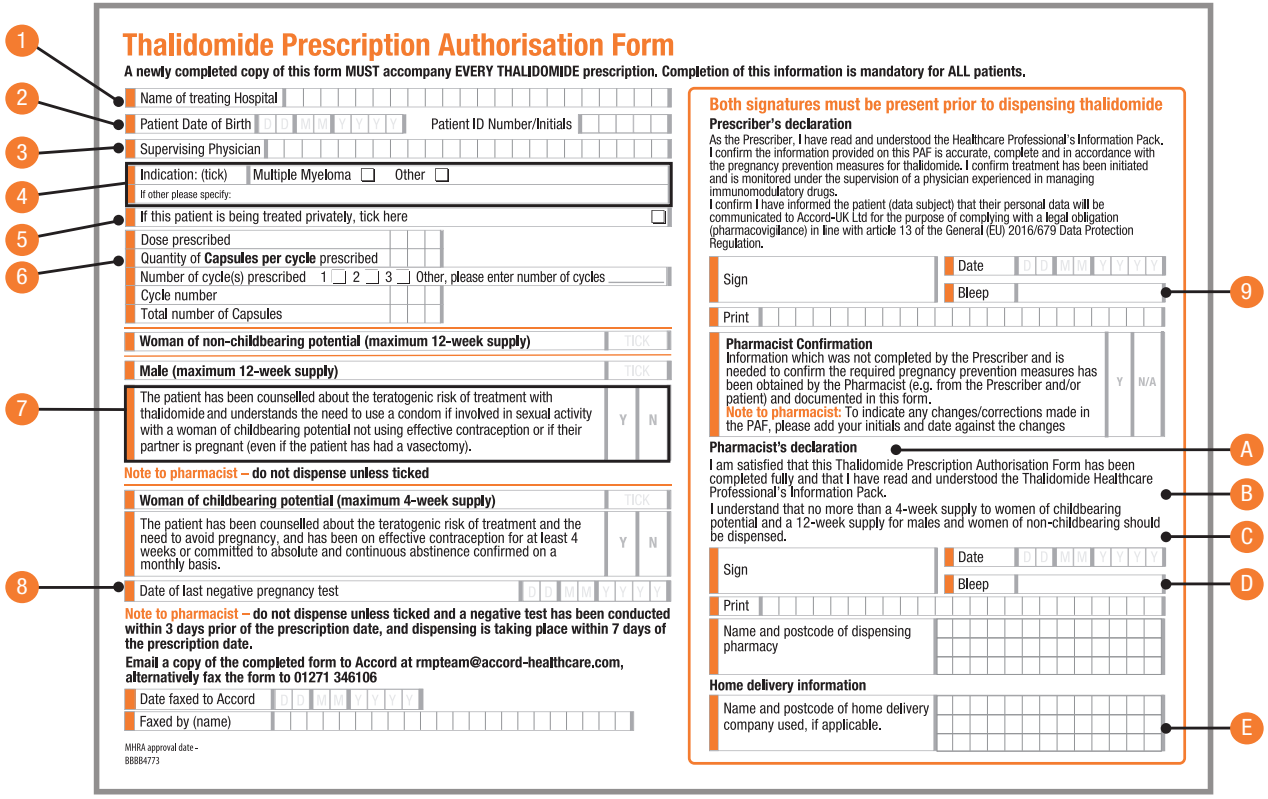
Prescription Authorisation Form (PAF) completion guide - Dual Format

This guide will help you to complete the Thalidomide Prescription Authorisation Form
The form is in the Healthcare Professional's Information Pack and must be completed each time you prescribe thalidomide for all patients.

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



Thalidomide Prescription Authorisation Form

A newly completed copy of this form MUST accompany EVERY THALIDOMIDE prescription. Completion of this information 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

4 Indication: (tick) Multiple Myeloma ☐ Other ☐
If other please specify:

5 If this patient is being treated privately, tick here ☐

6 Dose prescribed
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

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

Male (maximum 12-week supply) TICK

7 The patient has been counselled about the teratogenic risk of treatment with thalidomide 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). Y N

Note to pharmacist – do not dispense unless ticked

Woman of childbearing potential (maximum 4-week supply) TICK

The patient has been counselled about the teratogenic risk of treatment and 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. Y N

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

Note to pharmacist – do not dispense unless ticked 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.

Email a copy of the completed form to Accord at rmpteam@accord-healthcare.com, alternatively fax the form to 01271 346106

Date faxed to Accord (D D M M Y Y Y Y)
Faxed by (name)

MHRA approval date -
BBBB4773

Both signatures must be present prior to dispensing thalidomide

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 thalidomide. 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) Bleep 9

Print

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

Pharmacist's declaration A

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

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

Sign Date (D D M M Y Y Y Y) Bleep D

Print

Name and postcode of dispensing pharmacy

Home delivery information

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

MHRA approval date - 25/07/2022
BBBB4773

Instructions for prescribers

1. Print the full Hospital name where the patient is treated.
2. Print the patient's Date of Birth and Patient Identification Number or initials. 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 thalidomide , which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Programme.
5. If this patient is being treated privately, tick this box.
6. Enter the dose and quantity of capsules prescribed.
7. Complete this section appropriately to indicate that counselling and appropriate contraception has occurred. This is a requirement of the Pregnancy Prevention Programme.
8. 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 thalidomide must not be dispensed.
9. 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 contraceptive measures must be in place
   b. Prescription must be accompanied by a Prescription Authorisation Form
   c. For women of childbearing potential thalidomide can only be dispensed within 7 days of the prescription date.
   d. Only 4 weeks supply for women of childbearing potential, or 12 weeks supply for all other patients, of thalidomide can be dispensed at any one time
   e. The diagnosis and cycle number have been provided.

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 patient 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.

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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Dose prescribed

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

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Sign Date D D M M Y Y Y Y

Bleep

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Sign Date D D M M Y Y Y Y

Bleep

Print

Name and postcode of dispensing pharmacy

Home delivery information

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