



*Software and User Guide for REVLIMID® Patient-Physician  
Agreement Forms and REVLIMID® Patient Prescription Form*

**WARNINGS:**

**1. POTENTIAL FOR HUMAN BIRTH DEFECTS.**

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

**Special Prescribing Requirements**

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID® (lenalidomide), REVLIMID® (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED "REVASSIST®". UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID® (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE REVASSIST® PROGRAM.

**2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).**

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DEL 5q MYELODYSPLASTIC SYNDROMES HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY FOR DEL 5q MYELODYSPLASTIC SYNDROMES SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

**3. DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM.**

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID® (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY DESCRIBED IN CONJUNCTION WITH REVLIMID® (lenalidomide) MAY LESSEN THE POTENTIAL FOR VEIN THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT'S UNDERLYING RISK FACTORS.

You can get the information about REVLIMID® (lenalidomide) and the RevAssist® program on the internet at [www.REVLIMID.com](http://www.REVLIMID.com) or by calling the manufacturer's toll free number 1-888-423-5436.



# Overview

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## **IMPORTANT INFORMATION ABOUT RevAssist®**

- To avoid fetal exposure, REVLIMID® (lenalidomide) is only available under a special restricted distribution program called “RevAssist®”
  - Only prescribers registered with RevAssist® can prescribe REVLIMID® (lenalidomide)
  - Only RevAssist® contract pharmacies can dispense REVLIMID® (lenalidomide)
  - In order to receive REVLIMID® (lenalidomide), patients must enroll in RevAssist® and agree to comply with the requirements of the RevAssist® program
  - Information about REVLIMID® (lenalidomide) and the RevAssist® program can be obtained by calling the Celgene Customer Care Center toll-free at 1-888-423-5436, or at [www.REVLIMID.com](http://www.REVLIMID.com)
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Only the initial registration of patients is conducted via the REVLIMID® Patient-Physician Agreement Forms software.

Under this method of registering patients, the prescriber is provided with a CD-ROM containing the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software. The software is installed on a computer. The installation process is described in detail on page 4.

Based on information the prescriber enters for each patient, the software will determine the risk category in which the patient belongs.

After the patient-specific form is generated within the software, it is printed, initialed by the patient, signed and dated by the patient and the prescriber, then faxed to the Celgene Customer Care Center at 1-888-432-9325.

By registering a patient via the REVLIMID® Patient-Physician Agreement Forms software, the likelihood of human errors is reduced as well as the number of phone calls by the Celgene Customer Care Center to prescribers to gather additional information or to clarify information previously provided.

The CD-ROM contains 6 risk categories:

- Adult Males
- Male Children
- Adult Females of Childbearing Potential
- Adult Females Not of Childbearing Potential
- Female Children of Childbearing Potential
- Female Children Not of Childbearing Potential

## Installation on your PC computer

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To install the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software (Windows® version):

1. Insert CD-ROM into the computer's CD-ROM drive.
2. Click **Start**.
3. Click **Run**. The Run dialogue box appears.
4. In the Open box, type D:\setup.exe (replace "D" with the letter of your CD-ROM drive, if necessary). Then click **OK**.
5. Click **Next** at the installation welcome screen.
6. Choose a location in which to install the software. To accept the default location, click **Next**.
7. Click **Next** to install the software.
8. Wait for the computer to finish unpacking the files.
9. When the installation is complete, click **Finish**. Remove the CD-ROM.

Now that it is installed on your computer's hard drive, you do not need the CD-ROM to access the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software.

If your computer does not have a CD-ROM drive, please contact your Celgene Hematology Oncology Consultant or call the Celgene Customer Care Center at 1-888-423-5436.

Windows is a registered trademark of Microsoft Corporation in the United States and other countries.

## Installation on your Macintosh® computer

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To install the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software on Mac OS® X or higher:

1. Insert the CD-ROM into the computer's CD-ROM drive. The RevAssist® CD-ROM icon appears on the desktop.
2. Double-click on the **RevAssist** CD icon.
3. Double-click the **Install RevAssist** icon that appears. The Installation Wizard runs.
4. Install RevAssist®
  - a. If you are installing RevAssist® for the first time, select **I am installing RevAssist for the first time** and click **Finish**. This will install the application into the Applications system folder.
  - b. If you are currently using a previous version of RevAssist®, select **I already have RevAssist installed** and fill out the 2 boxes corresponding to the previous installation location and location of saved .reg files and click **Finish**.
5. If you upgraded an existing installation, you can run RevAssist® by clicking the same icon as before. If you are installing the software for the first time, click the **Finder** icon and navigate to the **RevAssist** folder (**Applications/Celgene/RevAssist**). The application is named RevAssist.
6. To remove the CD-ROM, press **Eject** or drag the CD icon to the trash.

*Mac OS 8 and OS 9 (Mac® Classic) users should complete these steps:*

1. Insert the CD-ROM into the computer's CD-ROM drive. The CD-ROM icon will appear on the desktop.
2. Double-click **RevAssist** CD icon. A window showing the CD contents will appear.
3. Double-click on the **classic** folder to open.
4. Select and copy the contents of this folder to the Mac Classic desktop. The application installed in the folder is named RevAssist.

Now that it is installed on your computer's hard drive, you do not need the CD-ROM to access the REVLIMID® Patient-Physician Agreement Forms and REVLIMID® Patient Prescription Form software.

If your computer does not have a CD-ROM drive, please contact your Celgene Hematology Oncology Consultant or call the Celgene Customer Care Center at 1-888-423-5436.

# Generating the REVLIMID® Patient-Physician Agreement Form

This section explains the process of generating the most appropriate of the 6 REVLIMID® Patient-Physician Agreement Forms that corresponds to the specific patient's demographic.

In this process, patient and prescriber information is entered into the Patient and Prescriber sections in the REVLIMID® Patient-Physician Agreement Form screen. Data from the Patient and Prescriber sections are then copied into the applicable REVLIMID® Patient-Physician Agreement Form. This form is printed, initialed by the patient, signed and dated by the patient and the prescriber, then faxed to the Celgene Customer Care Center (1-888-432-9325), where the patient registration process is completed by Customer Care Center Representatives.

To generate the REVLIMID® Patient-Physician Agreement Form:

**1. Windows® users:** Click **Start**. Move the cursor until **Programs** is highlighted, choose the **Celgene** folder, choose the **RevAssist Program** folder, choose **RevAssist Program**, and click once.

**Macintosh users:** Click the **Finder** icon and navigate to the **RevAssist** folder (**Applications/Celgene/RevAssist**). Double-click on the **RevAssist** icon.

**2.** The RevAssist® logo screen will be displayed (Figure 1). Click on the **REGISTER PATIENT** button.



**Figure 1**  
RevAssist® logo screen.

The REVLIMID® Patient-Physician Agreement Form screen (Figure 2) appears.

**Figure 2**  
REVLIMID® Patient-Physician Agreement Form screen.

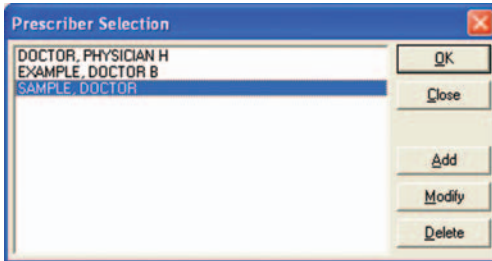
3. Enter information into each of the fields in the Patient Information section located in the upper portion of the REVLIMID® Patient-Physician Agreement Form screen. Note that instructions for each field are displayed at the bottom of the screen, and that:
- When typing in the year in the **DOB** field, all 4 digits are required
  - The **Date** field automatically fills in the current date. Alternatively, the date may be manually entered
  - The diagnosis can be filled in with the appropriate code by pressing **F2** when the cursor is placed in the **Diagnosis** field. Pressing **F2** displays the Diagnosis Code Search screen. The appropriate diagnosis can then be highlighted and transferred to the **Diagnosis** field on the REVLIMID® Patient-Physician Agreement Form screen by clicking **Accept**

If the patient is female, select the appropriate values for the menstruation, surgical menopause, and natural menopause fields.

Complete the **Prescriber Information** fields in the lower portion of the screen by filling out the **Last Name, First Name, and Middle Initial**.

Enter your 9-digit **DEA number** or your **Social Security number**.

The personal information for each prescriber needs to be entered only once. To generate subsequent forms for a prescriber, put your cursor in the prescriber **Last Name** field and press **F2**. A list of previously entered prescribers will appear (Figure 3). After highlighting a name, click **OK** to import that data into the REVLIMID® Patient-Physician Agreement Form.



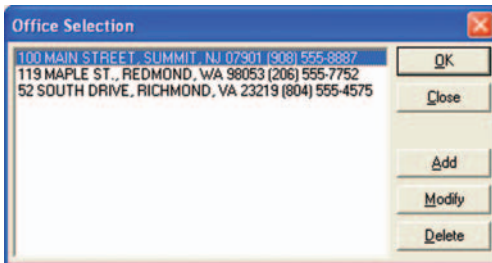
**Figure 3**  
Prescriber selection screen.

Prescribers may be added to this list by clicking **Add**. Prescriber's records may be modified (eg, name change) by clicking **Modify**, and deleted by clicking **Delete**.

Complete the **Prescriber Address** fields in the lower portion of the screen. The address information may be entered by filling out the **Street, City, State,** and **Zip** fields.

Enter the values for the **Phone Number** and **Fax Number** fields.

The address information for each prescriber needs to be entered only once. To generate subsequent forms for a prescriber, put your cursor in the prescriber **Street** field and press **F2**. A list of previously entered prescribers' addresses will appear (Figure 4). After highlighting an address, click **OK** to import that data into the REVLIMID® Patient-Physician Agreement Form. Prescriber's addresses may be added to this list by clicking **Add**. Prescriber's records may be modified (eg, address change) by clicking **Modify**, and deleted by clicking **Delete**.



**Figure 4**  
Office selection screen.

Note: After registering your first patient, use the same address in the **Prescriber Information** section if you are registering additional patients out of the same office.

- The REVLIMID® Patient-Physician Agreement Form will be automatically saved when submitted. Files may be saved manually by selecting **Save** from the File menu. (To retrieve the information at another time, press **F2** from the patient's **Last Name** field or select **Open** from the File menu, select the previously saved file, and either double-click the entry or click **OK**.)

The information for each patient needs to be entered only once. To access a patient's information from a completed form, open a new REVLIMID® Patient-Physician Agreement Form, place your cursor in the **Last Name** field, and press **F2** or select **Open** from the File menu. A list of previously entered patients will appear. Select the desired patient file, and either double-click the entry or click **OK**. Both the patient information and the information for the patient's prescriber will be imported into the REVLIMID® Patient-Physician Agreement Form.

- When the REVLIMID® Patient-Physician Agreement Form screen is complete, click **OK**. (A completed screen is shown in Figure 5.)

The screenshot shows a software window titled "REVLIMID Patient Registration and Consent Form Application". It contains two main sections: "Patient Information" and "Prescriber Information".

**Patient Information:**

- \* Last: FEMALE \* First: PATIENT MI: |
- \* Street: 123 MAIN ST
- \* City: EXAMPLE CITY \* State: NJ \* Zip: 12345
- \* Phone: 123 - 456 - 7890
- \* DOB: 12 / 30 / 1945 \* Sex: F \* SSN: - - -
- \* Date: 02 / 06 / 2007 \* Diagnosis: |
- \* Menstruating: No \* Surgical Menopause: No
- \* Has the patient completed natural menopause for at least 24 months: Yes

**Prescriber Information:**

- \* Last: SAMPLE \* First: DOCTOR MI: |
- \* DEA No: BD0122345 or \* SSN: - - - if you don't have a DEA
- \* Street: 100 MAIN STREET
- \* City: SUMMIT \* State: NJ \* Zip: 07901
- \* Phone: 908 - 555 - 8887 ext | \* Fax: 908 - 555 - 6521

At the bottom, there is a note: "\* denotes required field" and a checkbox for "Adult Female Not of Childbearing Potential" which is checked. There are "OK" and "Close" buttons.

Prescriber's Address - Street. Press F2 for list.

**Figure 5**  
REVLIMID® Patient-Physician Agreement Form screen (completed example).

6. The REVLIMID® Patient-Physician Agreement Form displays. The version of the form is dependent upon the patient's sex and childbearing status.
7. Print the REVLIMID® Patient-Physician Agreement Form. Select **Print** from the File menu or click **Print**. Note that the patient and the prescriber information previously entered into the REVLIMID® Patient-Physician Agreement Form screen has been copied into the form. Now inspect the form for accuracy and completeness.

At this point, the process of generating the REVLIMID® Patient-Physician Agreement Form is complete.

## Next steps

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1. Present the REVLIMID® Patient-Physician Agreement Form to the patient. In the course of the prescriber's counseling interview with the patient, the patient signifies his/her consent to the REVLIMID® (lenalidomide) treatment by writing his/her initials in each block of the form.

A sample of REVLIMID® Patient-Physician Agreement Form is shown in Figure 6.

2. Ensure that the **Patient signs and dates** the form in front of the prescriber.
3. Ensure that the **Prescriber signs and dates** the form.
4. Refrain from writing extraneous handwritten material on the REVLIMID® Patient-Physician Agreement Form other than the patient's initials and the patient's and prescriber's signatures.
5. Fax all pages of the REVLIMID® Patient-Physician Agreement Form to the Celgene Customer Care Center at 1-888-432-9325, as indicated on the bottom of the last page of the REVLIMID® Patient-Physician Agreement Form.

Once the patient is registered, Celgene will fax a confirmation letter to the prescriber so that both patient and prescriber can take their surveys as required.



# Generating the REVLIMID® Patient Prescription Form

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This section explains the process of generating a REVLIMID® Patient Prescription Form for use at a pharmacy that distributes REVLIMID®.

In this process, a registered patient's information is loaded into the REVLIMID® Patient Prescription Form screens and further information is entered about the patient, the prescriber, and the prescription. Data from these sections are then copied into the REVLIMID® Patient Prescription Form. This form is printed, signed, and dated by the prescriber, then faxed to the pharmacist, where the prescription is filled and confirmed with Celgene.

To generate the REVLIMID® Patient Prescription Form:

1. After you have finished with the print preview for the REVLIMID® Patient-Physician Agreement Form, you will automatically be prompted to write a REVLIMID® prescription for the patient. Alternately, you can open the RevAssist® Program again and click **WRITE PRESCRIPTION**. You will be prompted to choose a patient from the list.
2. The software then displays the first screen of the REVLIMID® Patient Prescription Form. Most of the information will be filled in automatically from the record of the registered patient. Enter missing information into the required fields or by using the pull-down menus. Note that instructions for each field are displayed at the bottom of the screen, and that:
  - **Other Phone Number** is optional
  - **Date Rx Needed** and **Language Preference** are required
  - **Patient Allergies** and **Other Current Medications** are required
3. After all information is entered on the first page, click **Next**.
4. The second screen of the REVLIMID® Patient Prescription Form is displayed. Enter required information about the prescriber, including **Physician State License Number**, **Office Contact Name**, and **Office Contact Phone Number**. This screen also contains space for information about **Primary** and **Secondary Insurance**.
5. After all information is entered on the second page, click **Next**.

6. The REVLIMID® Patient Prescription screen is displayed. Check the box that corresponds to the **Dose** in milligram (mg) strength and enter the **Quantity** of capsules. Fill in the medication **Directions** in the space provided. Be sure to select the correct choice of either **Dispense as Written** or **Substitution Permitted**, which will be indicated on the completed form for the pharmacist. Finally, enter the **Authorization Number** obtained from Celgene Customer Care Center.
7. When you are finished with these three screens, press **Print**.
8. The REVLIMID® Patient Prescription Form print preview window appears. The REVLIMID® Patient Prescription Form is now filled out with data collected on the previous screens.
9. Print the REVLIMID® Patient Prescription Form. Select **Print** from the File menu or click **Print**. Check the printed form for accuracy and completeness.

At this point, the procedure for generating the REVLIMID® Patient Prescription Form is complete.

## Next steps

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1. Ensure that the **Prescriber signs and dates** the REVLIMID® Patient Prescription Form where indicated in the Prescription section.
  2. Refrain from writing extraneous handwritten material on the REVLIMID® Patient Prescription Form other than the prescriber's signature.
  3. Fax the REVLIMID® Patient Prescription Form to the pharmacist, as indicated in "How to Fill a REVLIMID® (lenalidomide) Prescription" located on the second page.
- Follow the procedures on the second page of the REVLIMID® Patient Prescription Form to complete the business process.







**RevAssist<sup>®</sup>**

**For more information about REVLIMID<sup>®</sup> and RevAssist<sup>®</sup>,  
please call the Celgene Customer Care Center at 1-888-423-5436  
or visit [www.REVLIMID.com](http://www.REVLIMID.com)**

  
**Revlimid<sup>®</sup>**  
*(lenalidomide) capsules*



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