

# Talicia<sup>®</sup> Warranty Program Healthcare Provider Attestation Form

(To be completed by healthcare provider who prescribed Talicia)

## Patient Information

Patient Name (First/MI/Last): \_\_\_\_\_

Date of Birth (mm/dd/yyyy): \_\_\_\_\_

## Talicia Prescribing Healthcare Provider/Site of Care Information

Are you the healthcare provider who prescribed Talicia for this patient? (check one)     YES     NO

Prescribing Healthcare Provider Name (First/MI/Last): \_\_\_\_\_

Practice/Institution Name: \_\_\_\_\_

Address, City, State Zip: \_\_\_\_\_

NPI #: \_\_\_\_\_

State License #: \_\_\_\_\_

FAX # (with area code): \_\_\_\_\_

Contact Name: \_\_\_\_\_

Contact E-mail: \_\_\_\_\_

Contact Phone: \_\_\_\_\_

**PLEASE SEE COMPLETE PRESCRIBING INFORMATION  
AND IMPORTANT SAFETY INFORMATION ON FINAL PAGE.**

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I confirm that the patient completed the full 14-day course of therapy, taking Talicia as directed by the prescribing information (4 capsules every 8 hours with food). I also confirm a test for eradication of *H. pylori* infection was conducted approximately 4-6 weeks after the patient's last dose of Talicia using one of the following tests to demonstrate eradication of *H. pylori* infection: Urea Breath Test, Stool Antigen Test, CLO Test or tissue staining of stomach biopsy. (Important: Serology will not be accepted as a test for eradication of *H. pylori* infection.)

## Healthcare Provider Consent

I understand that completing this attestation form does not guarantee that a warranty remedy will be provided to my patient. I will comply with and abide by my State Practitioner Dispensing Laws for authorized Prescribers, when applicable. I understand that the information provided on this attestation form is subject to random audits and verification. I understand that my information may be provided to RedHill Biopharma for its administration and compliance of the Talicia Warranty Program. RedHill may change or cancel this program at any time. Should RedHill change or cancel the program, it will continue to honor valid warranty claims related to qualifying doses of Talicia dispensed during the period in which the program remained in effect.

## Healthcare Provider HIPAA and Telephone Consumer Protection Act (TCPA) Attestation

By my signature, I certify that the information I have provided above is true. I also certify that I have obtained any and all authorizations and consents from the patient or the patient's authorized personal representative necessary under HIPAA and state law to release protected health information, including that contained on this form, to RedHill and its employees or agents for purposes relating to the Talicia Warranty Program, including, assisting the patient with seeking a warranty claim for a RedHill medicine through the Talicia Warranty Program. I certify that I have obtained consent from the patient or the patient's caregiver to be contacted by RedHill, Talicia Warranty Program, and parties acting on their behalf, including calls made with an auto-dialer or prerecorded voice at the telephone number(s) provided regarding the purposes described above. I also give my permission to receive calls related to these services from RedHill, Talicia Warranty Program, and parties acting on their behalf, including calls made with an auto-dialer or prerecorded voice at the phone number(s) provided. I consent to providing my information to RedHill as it relates to the Talicia Warranty Program.

(To be completed by healthcare provider who prescribed Talicia)

Healthcare Provider Signature: \_\_\_\_\_

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

Healthcare Provider Email Address: \_\_\_\_\_

**PLEASE SEE COMPLETE PRESCRIBING INFORMATION  
AND IMPORTANT SAFETY INFORMATION ON FINAL PAGE.**

**PLEASE SEE COMPLETE PRESCRIBING INFORMATION  
AND IMPORTANT SAFETY INFORMATION BELOW.**

**IMPORTANT SAFETY INFORMATION**

Talicia contains omeprazole, a proton pump inhibitor (PPI), amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial. It is contraindicated in patients with known hypersensitivity to any of these medications, any other components of the formulation, any other beta-lactams or any other rifamycins.

Talicia is contraindicated in patients receiving delavirdine, voriconazole or rilpivirine-containing products.

Serious and occasionally fatal hypersensitivity reactions have been reported with the components of Talicia: omeprazole, amoxicillin and rifabutin.

Severe cutaneous adverse reactions (SCAR) such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the components of Talicia: rifabutin, amoxicillin, and omeprazole.

Acute Tubulointerstitial Nephritis has been observed in patients taking PPIs and penicillins.

*Clostridioides difficile*-associated diarrhea has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.

Talicia may cause fetal harm and is not recommended for use in pregnancy. It may also reduce the efficacy of hormonal contraceptives. An additional non-hormonal method of contraception is recommended when taking Talicia.

Talicia should not be used in patients with hepatic impairment or severe renal impairment.

Cutaneous lupus erythematosus and systemic lupus erythematosus have been reported in patients taking PPIs. These events have occurred as both new onset and exacerbation of existing autoimmune disease.

The most common adverse reactions ( $\geq 1\%$ ) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

Please also see complete Prescribing Information

You are encouraged to report side effects to the **FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**