

#### **NAT-TERIFLUNOMIDE**

#### **Targeted Follow-up Questionnaire**

for

#### **Interstitial Lung Disease**

Please send completed form back to Natco Pharma (Canada) Inc. by:

- email natco-drugsafety@innomar-strategies.com
- fax 1-833-761-0487

- mail Natco Pharma (Canada) Inc., 2000, Argentia Rd., Suite 200, Plaza 1, Mississauga, Ontario, L5N 1P7, Canada
Date of adverse event report:
Reporter is a Healthcare Professional  ☐ Yes ☐ No
Reporter name:
Reporter telephone #
Reporter email address:
Patient's initials: Sex M □ F □
Patient's Age:
Suspected Product Name: NAT-Teriflunomide
Dosage:
Start of Teriflunomide therapy: (DD/MMM/YYYY)
End of Teriflunomide therapy: (DD/MMM/YYYY)

Last Revised: February 18, 2022 Page 1 of 6



INDICATION & PATIENT MEDICAL HISTORY
The patient was prescribed teriflunomide for relapsing remitting multiple sclerosis (RRMS) sclerosis
The patient was diagnosed with multiple sclerosis on: (DD/MMM/YYYY)
The patient was prescribed teriflunomide for a condition other than RRMS: ☐ Yes ( <i>please describe</i> )
The patient was diagnosed with a condition other than RRMS on: (DD/MMM/YYYY)
Prior to starting teriflunomide, the patient was receiving the following medications: <i>Please</i> describe in detail
INTERSTITIAL LUNG DISEASE
DIAGNOSIS, OUTCOME & CAUSALITY
DIAGNOSIS, OUTCOME & CAUSALITY  The patient was diagnosed with
The patient was diagnosed with
The patient was diagnosed with  □ Interstitial lung disease
The patient was diagnosed with  ☐ Interstitial lung disease  Was the diagnosis confirmed?  ☐ Yes
The patient was diagnosed with  ☐ Interstitial lung disease  Was the diagnosis confirmed?  ☐ Yes ☐ No
The patient was diagnosed with  ☐ Interstitial lung disease  Was the diagnosis confirmed?  ☐ Yes ☐ No  If the answer is No, please skip to next section.
The patient was diagnosed with  Interstitial lung disease  Was the diagnosis confirmed?  Yes No  If the answer is No, please skip to next section.  Clinical presentation:

Last Revised: February 18, 2022 Page 2 of 6

Diagnosis of interstitial lung disease was confirmed based on:

☐ Computerized tomography (CT) scan

 $\hfill\Box$  Spirometry and diffusion capacity tests

☐ Blood tests

 $\ \square \ Echocardiogram$ 



INTERSTITIAL LUNG DISEASE
DIAGNOSIS, OUTCOME & CAUSALITY
☐ Oximetry tests
☐ Bronchoscopy ☐ Bronchoalveolar lavage
☐ Surgical biopsy
The diagnosis of interstitial lung disease was confirmed on: (DD/MMM/YYYY)
Interstitial lung disease is suspected but not confirmed
□ Yes
□ No
Interstitial lung disease is suspected based on:
□ Blood tests
☐ Computerized tomography (CT) scan
□ Echocardiogram
☐ Spirometry and diffusion capacity tests
☐ Oximetry tests ☐ Bronchoscopy
☐ Bronchoalveolar lavage
□ Surgical biopsy
The patient was suspected of having interstitial lung disease on (DD/MMM/YYYY)
Please provide details of blood tests, if applicable.
Triade provide details of blood tests, if applicable.
□ N/A
Please provide details of CT scan, if applicable.
□ N/A
Please provide details of echocardiogram if applicable.
□ N/A

Last Revised: February 18, 2022 Page **3** of **6** 



# INTERSTITIAL LUNG DISEASE **DIAGNOSIS, OUTCOME & CAUSALITY** Please provide details of spirometry and diffusion capacity tests, if applicable. □ N/A Please provide details of oximetry tests, if applicable. □ N/A Please provide details of bronchoscopy, if applicable □ N/A Please provide details of bronchoalveolar lavage, if applicable □ N/A Please provide details of surgical biopsy, if applicable □ N/A Please provide details of other diagnostic tests or procedures, if applicable. □ N/A Symptoms suggestive of interstitial lung disease, experienced by the patient (please check all that apply): ☐ Persistent cough ☐ Shortness of breath at rest ☐ Shortness of breath aggravated by exertion

Last Revised: February 18, 2022 Page 4 of 6



INTERSTITIAL LUNG DISEASE
DIAGNOSIS, OUTCOME & CAUSALITY
☐ Fever ☐ Weakness
☐ Discomfort in the chest
□ Other symptoms <i>(please describe in detail)</i>
Outcome
☐ Complete recovery
□ Recovering
☐ Recovered with sequelae
☐ Not recovered ☐ Fatal
□ Unknown
Please provide details of the treatment given for interstitial lung disease (please specify)
Is it reasonably possible that Teriflunomide could have caused any of the symptoms experienced by the patient?
□ Yes
□ No
Teriflunomide is suspected to be causative based on:
☐ Time to onset after starting the drug
☐ Time to recovery after stopping the drug
☐ The clinical pattern
☐ The exclusion of other causes of interstitial lung disease

Last Revised: February 18, 2022 Page **5** of **6** 



PATIENT'S RISK FACTORS FOR INTERSTITIAL LUNG DISEASE
(please check all that apply):
<ul> <li>□ The patient has a history of rheumatoid arthritis</li> <li>□ The patient has a history of scleroderma</li> <li>□ The patient has a history of dermatomyositis or polymyositis</li> <li>□ The patient has a history of mixed connective tissue disease</li> <li>□ The patient has a history of Sjogren's syndrome</li> <li>□ The patient has a history of sarcoidosis</li> <li>□ The patient has a history of gastroesophageal reflux disease</li> <li>□ The patient has a history of smoking</li> <li>□ The patient has been exposed to occupational and environmental toxins</li> <li>□ The patient has received radiation treatment in the chest area</li> <li>□ The patient has received chemotherapy</li> </ul>

Thank you for taking the time to complete this questionnaire.

Last Revised: February 18, 2022 Page **6** of **6**