

NAT-TERIFLUNOMIDE
Targeted Follow-up Questionnaire
for
Peripheral Neuropathy

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)

INDICATION & PATIENT MEDICAL HISTORY

The patient was prescribed teriflunomide for relapsing remitting multiple sclerosis (RRMS) sclerosis Yes

The patient was diagnosed with multiple sclerosis on: (DD/MMM/YYYY)

The patient was prescribed teriflunomide for a condition other than RRMS: Yes (***please describe***)

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: ***Please describe in detail***

PERIPHERAL NEUROPATHY DIAGNOSIS, OUTCOME & CAUSALITY

The patient was diagnosed with:

- Mononeuropathy
- Multiple mononeuropathy
- Polyneuropathy

Was the diagnosis confirmed?

- Yes
- No
- Unknown

If the answer is No, please skip to next section.

Diagnosis was confirmed based on:

- Blood tests
- Computerized tomography (CT) scan
- Magnetic resonance imaging (MRI)
- Electromyography (EMG)
- Autonomic reflex screen
- Deep tendon reflexes
- Nerve conduction studies
- Sweat test

PERIPHERAL NEUROPATHY
DIAGNOSIS, OUTCOME & CAUSALITY

- Sensory test
- Nerve biopsy
- Skin biopsy
- Other tests or procedures

The diagnosis of mononeuropathy was confirmed on: (DD/MMM/YYYY)

The diagnosis of multiple mononeuropathy was confirmed on: (DD/MMM/YYYY)

The diagnosis of polyneuropathy was confirmed on: (DD/MMM/YYYY)

Mononeuropathy/multiple mononeuropathy/ polyneuropathy is suspected but not confirmed

- Yes
- No
- Unknown

Mononeuropathy/multiple mononeuropathy/ polyneuropathy is suspected based on:

- Blood tests
- Computerized tomography (CT) scan
- Magnetic resonance imaging (MRI)
- Electromyography (EMG)
- Autonomic reflex screen
- Deep tendon reflexes
- Nerve conduction studies
- Sweat test
- Sensory test
- Nerve biopsy
- Skin biopsy
- Other tests or procedures

The patient was suspected of having mononeuropathy on: (DD/MMM/YYYY)

The patient was suspected of having multiple mononeuropathy on: (DD/MMM/YYYY)

The patient was suspected of having polyneuropathy on: (DD/MMM/YYYY)

Please provide details of blood tests, if applicable.

- N/A

**PERIPHERAL NEUROPATHY
DIAGNOSIS, OUTCOME & CAUSALITY**

Please provide details of CT scan, if applicable.

N/A

Please provide details of MRI, if applicable.

N/A

Please provide details of EMG, if applicable.

N/A

Please provide details of autonomic reflex screen, if applicable.

N/A

Please provide details of sweat test, if applicable.

N/A

Please provide details of sensory test, if applicable.

N/A

Please provide details of nerve biopsy, if applicable.

N/A

**PERIPHERAL NEUROPATHY
DIAGNOSIS, OUTCOME & CAUSALITY**

Please provide details of skin biopsy, if applicable.

N/A

Please provide details of other diagnostic tests or procedures, if applicable.

N/A

Symptoms suggestive of peripheral neuropathy, experienced by the patient (***please check all that apply***):

- Muscle weakness
- Numbness in hands
- Numbness in arms
- Numbness in feet
- Numbness in legs
- Tingling in the hands
- Tingling in the arms
- Tingling in the feet
- Tingling in the legs
- Lancinating pain in the hands
- Lancinating pain in the feet
- Burning pain in the hands
- Burning pain in the feet
- Sensitivity to touch
- Heat intolerance
- Excessive sweating
- Inability to sweat
- Digestive issues (***please describe in detail***)
- Bladder issues (***please describe in detail***)
- Bowel issues (***please describe in detail***)
- Dizziness or light-headedness
- Other symptoms (***please describe in detail***)

**PERIPHERAL NEUROPATHY
DIAGNOSIS, OUTCOME & CAUSALITY**

Outcome

- Complete recovery
- Recovering
- Recovered with sequelae
- Not recovered
- Fatal
- Unknown

Please provide details of the treatment given for mononeuropathy/multiple mononeuropathy/polyneuropathy (*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 peripheral neuropathy

PATIENT'S RISK FACTORS PERIPHERAL NEUROPATHY

(please check all that apply)

- The patient has a family history of neuropathy
- The patient has diabetes
- The patient has a history of alcoholism
- The patient has a history of vitamin B deficiencies
- The patient has a history of Lyme disease
- The patient has a history of shingles
- The patient has a history of Epstein-Barr virus infection
- The patient has a history of hepatitis B or hepatitis C
- The patient has a history of HIV
- The patient has a history of rheumatoid arthritis
- The patient has a history of lupus erythematosus
- The patient has a history of another autoimmune disease (*please specify*)

- The patient has a history of kidney disease
- The patient has a history of liver disease
- The patient has a history of thyroid disorder
- The patient has a history of injury or pressure on the nerve from a motor vehicle accident, fall or sports injury (***please specify***)
- The patient has a history of tumour (cancerous or non-cancerous)
- The patient has a history of connective tissue disorder (***please specify***)
- The patient has a history of bone marrow disorder (***please specify***)
- The patient has a history of exposure to toxins (***please specify***)
- The patient has received chemotherapy (***please specify***)
- The patient performs repetitive motions (***please specify***)

Thank you for taking the time to complete this questionnaire.