

NAT-TERIFLUNOMIDE
Targeted Follow-up Questionnaire
for
Pancreatic Disorders

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***

PANCREATIC DISORDERS DIAGNOSIS, OUTCOME & CAUSALITY

The patient was diagnosed with

- Acute pancreatitis
- Chronic pancreatitis
- Other pancreatic disorder (***please specify***)

Was the diagnosis confirmed?

- Yes
- No

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

Diagnosis of acute pancreatitis/chronic pancreatitis/other pancreatic disorder was confirmed based on:

- Blood tests
- Abdominal ultrasound
- Computerized tomography (CT) scan
- Magnetic resonance imaging (MRI)
- Endoscopic ultrasound
- Stool tests
- Other tests or procedures

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

PANCREATIC DISORDERS
DIAGNOSIS, OUTCOME & CAUSALITY

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

The diagnosis of "other pancreatic disorder" (***please specify***) was confirmed on:
(DD/MMM/YYYY)

Acute pancreatitis/chronic pancreatitis/other pancreatic disorder is suspected but not confirmed

- Yes
 No

Acute pancreatitis/chronic pancreatitis/other pancreatic disorder is suspected based on:

- Blood tests
 Abdominal ultrasound
 Computerized tomography (CT) scan
 Magnetic resonance imaging (MRI)
 Endoscopic ultrasound
 Stool tests
 Other

The patient was suspected of having acute pancreatitis on (DD/MMM/YYYY)

The patient was suspected of having chronic pancreatitis on (DD/MMM/YYYY)

The patient was suspected of having "other pancreatic disorder" (***please specify***) on:
(DD/MMM/YYYY)

Please provide details of blood tests, if applicable.

- N/A

Please provide details of abdominal ultrasound, if applicable.

- N/A

Please provide details of CT scan, if applicable.

- N/A

PANCREATIC DISORDERS
DIAGNOSIS, OUTCOME & CAUSALITY

Please provide details of MRI, if applicable.

N/A

Please provide details of endoscopic ultrasound, if applicable.

N/A

Please provide details of stool tests, if applicable.

N/A

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

N/A

Symptoms suggestive of acute pancreatitis/chronic pancreatitis/other pancreatic disorder, experienced by the patient (***please check all that apply***):

- Tenderness when touching the abdomen
- Upper abdominal pain
- Abdominal pain that feels worse after eating
- Abdominal bleeding
- Steatorrhea
- Fever
- Malaise
- Jaundice
- Fast heartbeat
- Nausea
- Vomiting
- Weight loss
- Other symptoms (***please describe in detail***)

**PANCREATIC DISORDERS
DIAGNOSIS, OUTCOME & CAUSALITY**

Outcome

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

Please provide details of the treatment given for acute pancreatitis /chronic pancreatitis/other pancreatic disorder (***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 pancreatic disorder

PATIENT'S RISK FACTORS FOR PANCREATIC DISORDERS

(please check all that apply):

- The patient has a previous occurrence of acute pancreatitis
- The patient has a family history of pancreatitis
- The patient has a history of gallstones
- The patient has a history of hypercalcemia
- The patient has a history hypertriglyceridemia
- The patient has diabetes
- The patient has a history of alcoholism

- The patient has a history of cigarette smoking
- The patient has had abdominal surgery or abdominal trauma. *Date (DD/MMM/YYYY)*
- The patient is obese
- The patient was receiving concomitant medications that are known to cause drug-induced pancreatitis

Thank you for taking the time to complete this questionnaire.