NAT-TERIFLUNOMIDE **Targeted Follow-up Questionnaire** **for** **Hepatic Effects**
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***

HEPATIC EFFECTS
DIAGNOSIS, OUTCOME & CAUSALITY

The patient was diagnosed with

☐ Drug-induced liver injury (unknown specificity)

☐ Drug-induced hepatocellular injury

☐ Drug-induced cholestatic injury

Was the diagnosis confirmed?

☐ Yes
☐ No

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

Clinical presentation of confirmed drug-induced liver injury

(please check the clinical phenotype that applies to your patient)

☐ Acute hepatic necrosis

☐ Acute (hepatocellular) hepatitis

☐ Cholestatic hepatitis

☐ Mixed hepatitis

☐ Cholestatic hepatitis

HEPATIC EFFECTS
DIAGNOSIS, OUTCOME & CAUSALITY

☐ Bland cholestasis

☐ Serum enzyme elevations without jaundice

☐ Acute fatty liver with lactic acidosis

☐ Non-alcoholic fatty liver

☐ Chronic hepatitis

☐ Sinusoidal obstruction syndrome

☐ Nodular regenerative hyperplasia

☐ Hepatic tumors (*please specify: hepatic adenoma, hepatocellular carcinoma, etc.*)

Clinical outcomes *(please check any that apply to your patient)*

☐ Immunoallergic hepatitis

☐ Autoimmune hepatitis

☐ Vanishing bile duct syndrome

☐ Cirrhosis

☐ Acute liver failure

Diagnosis was confirmed based on:

☐ Blood tests
☐ Liver biopsy
☐ Ultrasound of liver

The diagnosis of drug-induced liver injury (unknown specificity) was confirmed on: (DD/MMM/YYYY)

The diagnosis of drug-induced hepatocellular injury was confirmed on: (DD/MMM/YYYY)

The diagnosis of drug-induced cholestatic injury was confirmed on: (DD/MMM/YYYY)

Drug-induced liver injury (unknown specificity)/ drug-induced hepatocellular injury/ drug-induced cholestatic injury is suspected but not confirmed

☐ Yes
☐ No

Drug-induced liver injury (unknown specificity)/ drug-induced hepatocellular injury/ drug-induced cholestatic injury is suspected based on:

☐ Blood tests
☐ Liver biopsy

HEPATIC EFFECTS **DIAGNOSIS, OUTCOME & CAUSALITY**
☐ Ultrasound of liver The patient was suspected of having drug-induced liver injury (unknown specificity) on: (DD/MMM/YYYY) The patient was suspected of having drug-induced hepatocellular injury on: (DD/MMM/YYYY) The patient was suspected of having drug-induced cholestatic injury on: (DD/MMM/YYYY)
Please provide details of tests for serum alanine (ALT), serum aspartate aminotransferase (AST), serum alkaline phosphatase (ALP), serum gamma glutamyl transpeptidase (GGT), serum bilirubin, prothrombin time, antinuclear antibody (ANA), immunoglobulins, and other blood tests, as applicable. ☐ N/A
Please provide details of liver biopsy, if applicable. ☐ N/A
Please provide details of ultrasound of the liver, if applicable. ☐ N/A
Please provide details of other diagnostic tests or procedures, if applicable. ☐ N/A
Symptoms suggestive of hepatic dysfunction, experienced by the patient ***(please check all that apply)***: ☐ Nausea ☐ Vomiting ☐ Abdominal pain ☐ Fatigue

HEPATIC EFFECTS **DIAGNOSIS, OUTCOME & CAUSALITY**
☐ Anorexia ☐ Jaundice ☐ Dark urine ☐ Fever ☐ Rash ☐ Arthralgia ☐ Other symptoms ***(please describe in detail)***
Outcome ☐ Complete recovery ☐ Recovering ☐ Recovered with sequelae ☐ Not recovered ☐ Fatal ☐ Unknown
Please provide details of the treatment given for drug-induced liver injury (unknown specificity)/ drug-induced hepatocellular injury/ drug-induced cholestatic injury ***(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: injury pattern and clinical phenotype ☐ The exclusion of other causes of liver injury

PATIENT'S RISK FACTORS FOR HEPATIC EFFECTS
(please check all that apply): ☐ The patient has underlying chronic liver disease ☐ The patient has received concomitant medications that can potentially induce liver injury ☐ The patient was pregnant ☐ The patient has a history of cardiovascular disease ☐ The patient has a history of respiratory disease ☐ The patient has had an allergic response to a structurally related medication ☐ The patient has a history of autoimmune disease ☐ The patient has a history of cancer ☐ The patient has a history of alcoholism ☐ The patient has received acupuncture ☐ The patient has had surgery *(please specify)* ☐ The patient has travelled to Africa or Asia

Thank you for taking the time to complete this questionnaire.