

### Healthcare Professional Specific Adverse Reaction Follow Up Form

This questionnaire is intended to follow-up on specific adverse reactions regarding opioid-related harms for your patient.

<b>HEALTHCARE PROFESSIONAL SPECIFIC ADVERSE REACTION FOLLOW UP FORM</b>	
<b>MINT CONTACT INFORMATION:</b>  <b>Telephone:</b> +1 877-398-9696  <b>Fax:</b> +1 647-723-7696  <b>Email:</b> drugsafety@mintpharmaceuticals.com	<b>FOR MINT USE ONLY:</b>  Reference case no:  Mint Received Date: _____ (YYYY-MM-DD)
<b>Reporter Information</b>	
1. Reporter Name	
2. Reporter <input type="checkbox"/> Qualification Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other health professional: _____	
3. Contact Information  Email: _____  Phone: _____  Address: _____	
4. Type of Report <input type="checkbox"/> Initial: _____ (YYYY-MM-DD) <input type="checkbox"/> Follow-up: _____ (YYYY-MM-DD)	
5. Date of this Report  _____ (YYYY-MM-DD)	
<b>Patient Information</b>	
1. Initials or Unique Identifier (if available)	
2. Age	
3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	

4. Relevant Medical History/Risk Factors (e.g., pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

5. Relevant Tests/Laboratory data

Lab Test:	Lab Test Date: (YYYY-MM-DD)	Results:	Normal Range:	Comments:

**MINT-TRAMADOL/ACETAMINOPHEN Therapy Information**

1. Tramadol/Acetaminophen dosage

2. Tramadol/Acetaminophen route of administration

3. Indication

4. Accidental Exposure  Yes OR  No

5. Duration of Treatment

Start date:

End date:

Ongoing?

a) Long term exposure (greater than 12 weeks):  Yes OR  No

6. Concomitant medications/treatments/supplements

Product Name:	Dosage Regimen	Start Date: (YYYY-MM-DD)	Stop Date/Ongoing: (YYYY-MM-DD)	Indication of Use:

## Adverse Reaction Information

1. Important identified risks (select all that apply):

Abuse/ Misuse

Does the patient display any of the following signs or symptoms of **abuse/ misuse** (check all that apply):

- Pinpoint (very small) pupils
- Changes in appetite
- Nausea
- Vomiting
- Drowsiness
- Slurred speech
- Headaches
- Impaired coordination
- Death
- Other (please specify): \_\_\_\_\_

Accidental Exposure

Does the patient display any of the following signs or symptoms of **accidental exposure** (check all that apply)

- Feelings of euphoria and relaxation
- False sense of well-being
- Confusion
- Sedation
- Drowsiness
- Dizziness/ lightheadedness
- Nausea and vomiting
- Constipation
- Respiratory depression or arrest
- Death
- Other (please specify): \_\_\_\_\_

Death

Interaction with alcohol, benzodiazepines, and other CNS depressants

Is the patient taking any of the following medications

- Alcohol
- Benzodiazepines
- Other central nervous system (CNS) depressants
- Other (please specify): \_\_\_\_\_

Life-threatening respiratory depression

Has the patient experienced **life-threatening respiratory depression** (symptoms can include slowed breathing, long pauses between breaths, or shortness of breath)?

- Yes
- No

Neonatal Opioid Withdrawal Syndrome (NOWS)

Has the infant experienced **Neonatal Opioid Withdrawal Syndrome (NOWS)**?

- Yes
- No
- Not applicable

If yes, what following signs or symptoms of **Neonatal Opioid Withdrawal Syndrome** did the patient display (check all that apply):

- Body shakes (tremors), seizures (convulsions), overactive reflexes (twitching) and tight muscle tone
- Fussiness, excessive crying or having a high-pitched cry
- Poor feeding or sucking or slow weight gain
- Breathing problems, including breathing really fast
- Fever, sweating or blotchy skin
- Trouble sleeping and lots of yawning
- Diarrhea or throwing up
- Stuffy nose or sneezing
- Other (please specify): \_\_\_\_\_

Opioid Use Disorder (Addiction)

Has the patient shown any signs or symptoms of tramadol **addiction** (check all that apply):

- No signs of addiction
- Unable to Control Tramadol Use (The individual may attempt to reduce the dosage or is continue the tramadol, but cannot)
- Experiencing Substance Cravings
- Doctor Shopping (When the refills are denied, the individual may seek out other physicians to acquire new prescriptions for the tramadol)
- Experiencing Withdrawal Symptoms
- Other (please specify): \_\_\_\_\_

Overdose

Has the patient shown any symptoms of **overdose** (check all that apply):

- Decreased size of the pupil (the black circle in the center of the eye)
- Difficulty breathing
- Slow or shallowing breathing
- Extreme drowsiness or sleepiness
- Unable to respond or wake up
- Slowed heartbeat
- Muscle weakness
- Cold, clammy skin
- Other (please specify): \_\_\_\_\_

Physical and psychological dependence/tolerance (Drug withdrawal syndrome)/ Withdrawal

Has the patient shown signs or symptoms of **physical and psychological dependence/tolerance or withdrawal** (check all that apply)?

- Feeling agitated or anxious
- Panic attacks
- Feeling your heartbeat (palpitations)
- Difficulty sleeping
- Shaking
- Sweating
- Body aches
- Feeling restless
- Other (please specify): \_\_\_\_\_

Comments (if any):

<p>2. Important potential risks (select all that apply): Medication error</p> <p><input type="checkbox"/> Off-label use (Ex. pediatric/adolescent populations, restless legs syndrome, antidepressant, premature ejaculation), please specify: _____</p> <p><input type="checkbox"/> Diversion</p>
<p>3. Adverse Reaction Description:</p>
<p>4. Onset Date of Reaction _____ (YYYY-MM-DD)</p>
<p>5. Therapy Stop Date _____ (YYYY-MM-DD)</p>
<p>6. Outcome:</p> <p><input type="checkbox"/> Recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Not Recovered <input type="checkbox"/> Recovered with Sequelae <input type="checkbox"/> Recovering</p> <p><input type="checkbox"/> OR Unknown</p>
<p>7. Was it treated?</p>
<p>8. Reporter Causality:</p> <p><input type="checkbox"/> Certain <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Conditional OR <input type="checkbox"/> Unassessable</p>
<p>9. Additional Information or Comments:</p>

<p>Reporter Signature:</p>	<p>Date (YYYY-MM-DD):</p>
<p><b>FOR MINT USE ONLY:</b></p> <p>Signature:</p>  <p>Print Name:</p>	<p>Date (YYYY-MM-DD):</p>