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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.

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

2. Important potential risks (select all that

☐ apply): Medication error

☐ Off-label use (Ex. pediatric/adolescent populations, restless legs syndrome, antidepressant, premature ejaculation), please specify: _____

☐ Diversion

3. Adverse Reaction Description:

4. Onset Date of Reaction _____ (YYYY-MM-DD)

5. Therapy Stop Date _____ (YYYY-MM-DD)

6. Outcome:

☐ Recovered ☐ Fatal ☐ Not Recovered ☐ Recovered with Sequelae ☐ Recovering ☐ OR Unknown

7. Was it treated?

8. Reporter Causality:

☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Conditional OR ☐ Unassessable

9. Additional Information or Comments:

Reporter Signature:	Date (YYYY-MM-DD):
FOR MINT USE ONLY: Signature: Print Name:	Date (YYYY-MM-DD):