



Risk Management Plan
for Tapentadol

18 Jun 2019

Annex 4 - Specific adverse drug reaction follow-up forms

Structured questionnaire on abuse, dependence and diversion

Structured questionnaire on suicidal ideation and behavior

(6 pages)



Manufacturer Control Number


Questionnaire for the follow up of ICSRs of drug diversion, drug abuse, drug dependence, and drug withdrawal for tapentadol								
Patient Identification	Initials <small>(first, last)</small>	Country	Date of birth <small>(DD-MM-YYYY)</small>	Age <small>(years)</small>	Sex <small>(F, M)</small>	Height <small>(cm)</small>	Weight <small>(kg)</small>	Profession
Report Type	Drug diversion <input type="checkbox"/> Drug abuse <input type="checkbox"/> Drug dependence <input type="checkbox"/> Drug withdrawal <input type="checkbox"/> Health care professional <input type="checkbox"/> non healthcare professional <input type="checkbox"/>							
Suspected Drug	Compound <small>(Substance or trade name)</small>	Formulation	Daily dosage	Start date <small>(DD-MM-YYYY)</small>	Stop date <small>(DD-MM-YYYY)</small>			
Acquisition	Acquisition: 1. Prescription (special narcotic prescription) <input type="checkbox"/> 2. Multiple prescriptions (from different physicians) <input type="checkbox"/> 3. Prescription intended for another person <input type="checkbox"/> 4. Abroad <input type="checkbox"/> 5. Online <input type="checkbox"/> 6. From friends/family <input type="checkbox"/> 7. Sample package received from physician <input type="checkbox"/> 8. Black market <input type="checkbox"/> 9. Faked prescription <input type="checkbox"/> 10. Theft / Burglary <input type="checkbox"/> 11. Other <input type="checkbox"/> Preferred type of acquisition:							
Drug Diversion	Reported term:							
	Diversion for personal need (e.g., recreational purposes): yes <input type="checkbox"/> no <input type="checkbox"/> If yes, please specify: Year of first diversion _____ Number of days of consumption during the last 30 days of intake _____							
	Diversion for secondary purchase: yes <input type="checkbox"/> no <input type="checkbox"/>							

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	Questionnaire for the follow up of ICSRs of drug diversion, drug abuse, drug dependence, and drug withdrawal	Manufacturer Control Number
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Drug abuse	Reported term:			
	Abuse criteria: (<u>Underlined criteria</u> match European Union Directive 2001/83/EC stipulations)			
	<input type="checkbox"/>	<u>persistent</u>		
	<input type="checkbox"/>	<u>sporadic</u>		
	<input type="checkbox"/>	<u>intentional</u>		
	<input type="checkbox"/>	per prescription; if yes, please specify indication:		
	<input type="checkbox"/>	<u>excessive use</u> ; if yes, please indicate the latest daily dosage:		
	<input type="checkbox"/>	dose escalation during the time of abuse; if yes, please indicate the dosage at the beginning of abuse:		
	<input type="checkbox"/>	<u>harmful physical or psychological effects</u> ; if yes, please specify:		
	History of abuse:			
Year of first substance abuse:				
Please specify which substance was firstly abused:				
Specification of substances abused during the last 30 days:				
Number of days of consumption during the last 30 days of intake:				
Single substance abuse yes <input type="checkbox"/> no <input type="checkbox"/>		Multiple substance abuse yes <input type="checkbox"/> no <input type="checkbox"/>		
If multiple substance abuse, please specify other substances (e.g., alcohol, CNS active substances, illicit drugs)				
1.)				
2.)				
3.)				
4.)				
Reasons for intake:				
Anxiolysis <input type="checkbox"/>		Avoidance of withdrawal symptoms <input type="checkbox"/>		
Euphorization <input type="checkbox"/>		Increasing performance <input type="checkbox"/>		
Modulating effects of other drugs <input type="checkbox"/>		Pain relief <input type="checkbox"/>		
Mood lifter/ mood enhancer <input type="checkbox"/>		Sedation <input type="checkbox"/>		
Stimulation <input type="checkbox"/>		Other <input type="checkbox"/>		
Route of administration:				
Inhalation <input type="checkbox"/>		Injection <input type="checkbox"/>		
Per os <input type="checkbox"/>		other <input type="checkbox"/>		

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Drug dependence	Reported term:	
	Dependence criteria: (At least 3 within the last 12 months for a diagnosis of drug dependence according to DSM-IV classification) <ul style="list-style-type: none"> <input type="checkbox"/> Tolerance (increased dosages to achieve same effect; diminished drug effect with constant dosage) <input type="checkbox"/> Withdrawal (drug craving; physiological withdrawal such as vegetative symptoms) <input type="checkbox"/> Excessive use (Substance is taken in larger amounts or over a longer period than was intended) <input type="checkbox"/> Persistent desire or unsuccessful efforts to cut down or control substance use <input type="checkbox"/> A great deal of time is spent for <ul style="list-style-type: none"> ▪ obtaining the substance (e.g. visiting multiple doctors or driving long distances) ▪ using the substance (e.g. chain-smoking) ▪ recovering from its effects <input type="checkbox"/> Important social, occupational, or recreational activities are given up or reduced because of substance use <input type="checkbox"/> Substance use is continued despite knowledge of persistent or recurrent physical or psychological problems that are likely to have been caused or exacerbated by the substance 	
Drug withdrawal	Reported term:	
	Time of cessation of suspected drug (hh:mm; DD-MM-YYYY):	
	Time of first withdrawal symptoms (hh:mm; DD-MM-YYYY):	
	End of withdrawal symptoms (hh:mm; DD-MM-YYYY):	
	Withdrawal symptoms:	
	Re-exposure to suspected or alternative drug): yes <input type="checkbox"/> no <input type="checkbox"/>	
	Effect of re-exposure:	

Date:

Signature:



Questionnaire for the follow up of ICSRs of suicidal ideation and behavior and intentional overdoses

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1 EVENT SPECIFICATION

Did the patient experience suicidal ideation or behavior?

<input type="checkbox"/> Suicidal ideation (SI)	<input type="checkbox"/> Suicidal behavior	<input type="checkbox"/> No <input type="checkbox"/> Unknown
<input type="checkbox"/> SI passive (wish to be dead)	<input type="checkbox"/> Completed suicide	<input type="checkbox"/> Intentional overdose
<input type="checkbox"/> SI active, no method, intend or plan	<input type="checkbox"/> Suicide attempt	<input type="checkbox"/> Self-injury without suicidal intent
<input type="checkbox"/> SI active with method, no intend or plan	<input type="checkbox"/> Interrupted attempt	<input type="checkbox"/> Other
<input type="checkbox"/> SI active with method and intend, no plan	<input type="checkbox"/> Aborted attempt	
<input type="checkbox"/> SI active with method, intend and plan	<input type="checkbox"/> Preparatory actions toward imminent suicidal behavior	

For information on the classification refer to [Appendix A](#)

Was the patient on treatment with the medicinal product prior to the event?

Yes → for how long? _____ no unknown

Was the dose of the Medicinal Product recently changed?

Yes no unknown If yes specify (timing, dosing details)

Did the patient take the medicinal product in a dose higher than the maximal recommended dose specified in the Package Insert? Yes no unknown

If yes:

Medicinal product only; please state the dose higher than recommended: _____

Multiple drug overdose; please list drugs taken (if known): _____

Was medicinal product overdose accidental or intentional? accidental intentional

Was overdose recommended by the prescribing physician? yes no

2 RISK FACTORS

2.1 Prior psychiatric disease present? yes no unknown

(e.g. Depression or bipolar (manic-depressive) disorder; Alcohol or substance abuse or dependence; Schizophrenia; Borderline or antisocial personality disorder; Conduct disorder (in youth); Psychotic disorders; psychotic symptoms in the context of any disorder; Anxiety disorders; Impulsivity and aggression, especially in the context of the above; mental disorders)

Diagnosis	Start date	Course of disease: stable/recurrent/recent worsening	Treatment	Treatment start	Recent changes in treatment

Previous suicide attempt: yes → when? _____ how many? _____ no unknown

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2.2 Medical history except psychiatric disease

History/ presence of pain? Yes no unknown

Was **pain relief satisfactory** at the time of event? Yes no →NRS? _____ unknown

Did recent changes to the course of diseases occur? Yes no unknown

If yes specify _____

2.3 Co-Medications

Recent changes in co-medication? Yes no unknown

If yes specify: _____

Possible contribution of co-medication to the event? Yes no unknown

If yes specify: _____

2.4 Situational risk factors:

Where there situational risk factors prior or at the time of event? No Unknown
(Please tick all that apply):

- | | | |
|---|--|---|
| <input type="checkbox"/> Loss of job
<input type="checkbox"/> Divorce / separation from partner (please specify)

<input type="checkbox"/> Abuse of alcohol
<input type="checkbox"/> Access to lethal methods during a period of increased risk | <input type="checkbox"/> Death of relative/friend;
<input type="checkbox"/> Serious relationship conflicts

<input type="checkbox"/> Drug abuse
<input type="checkbox"/> Exposure to another person's suicide or sensationalized accounts of suicide | <input type="checkbox"/> Financial problems
<input type="checkbox"/> Harassment or bullying

<input type="checkbox"/> Problems with the law
<input type="checkbox"/> Other, please describe |
|---|--|---|

2.5 Family history

Family history of attempted or completed suicide Yes no unknown

Family history of child maltreatment Yes no unknown

Please continue on a separate page in case the space is not sufficient.



Questionnaire for the follow up of ICSRs of suicidal ideation and behavior and intentional overdoses - Appendix A

Appendix A: SUICIDAL IDEATION AND BEHAVIOR CATEGORIES AND DEFINITIONS (Posner, Oquendo, et al. 2007)

Suicidal Ideation

Passive suicidal ideation: wish to be dead

Patient has thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.

Active suicidal ideation: nonspecific (no method, intent, or plan)

General nonspecific thoughts of wanting to end one's life or commit suicide (e.g., "I've thought about killing myself") without general thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.

Active suicidal ideation: method, but no intent or plan

Patient has thoughts of suicide and has thought of at least one method during the assessment period. This situation is different than a specific plan with time, place, or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where, or how I would actually do it . . . and I would never go through with it."

Active suicidal ideation: method and intent, but no plan

Active suicidal thoughts of killing oneself, and patient reports having some intent to act on such thoughts, as opposed to "I have the thoughts but I definitely will not do anything about them."

Active suicidal ideation: method, intent, and plan

Thoughts of killing oneself with details of plan fully or partially worked out and patient has some intent to carry it out (i.e., some degree of intent is implicit in the concept of plan).

Suicidal Behavior

Completed suicide

A self-injurious behavior that resulted in fatality and was associated with at least some intent to die as a result of the act. Evidence that the individual intended to kill him- or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.

Suicide attempt

A potentially self-injurious behavior, associated with at least some intent to die as a result of the act. Evidence that the individual intended to kill him- or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance. A suicide attempt may or may not result in actual injury.

Interrupted suicide attempt

When the person is interrupted (by an outside circumstance) from starting a potentially self-injurious act (if not for that, actual attempt would have occurred).

Aborted suicide attempt

When person begins to take steps toward making a suicide attempt, but stops before actually engaging in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops before being stopped by something else.

Preparatory acts toward imminent suicidal behaviors

This category can include anything beyond a verbalization or thought, but it stops short of a suicide attempt, an interrupted suicide attempt, or an aborted suicide attempt. This might include behaviors related to assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note).

Self-Injurious Behavior Without Suicidal Intent

Self-injurious behavior associated with no intent to die. The behavior is intended purely for other reasons, either to relieve distress (often referred to as *self-mutilation* (e.g. superficial cuts or scratches, hitting or banging, or burns)) or to effect change in others or the environment.