

Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Midazolam for agitation Series 13

Palliative Care Clinical Studies Collaborative (PaCCSC)
RAPID Pharmacovigilance in Palliative Care
The case report form (CRF) is to be completed in compliance with
PaCCSC Standard Operating Procedures (SOP)

Midazolam for Agitation - Baseline

Demographics

Gender Male
 Female

Age

Weight (kg)
Height (cm)

Primary life limiting illness

- Advanced cancer – please specify type of cancer: _____
- End stage renal failure
- Hepatic failure
- Neurodegenerative disease
- AIDS
- Cardiac failure
- Respiratory failure
- Other

Please specify Other Life limiting Illness _____

Palliative Care Phase?

- Stable Unstable Deteriorating Terminal

1, Stable: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.

2, Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.

3, Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.

4, Terminal Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Laboratory tests (fill those available)

Test	Value
Serum albumin	
International normalised ratio (INR)	
C-reactive protein (CRP)	
Calculated creatinine clearance (CCr) or eGFR	
Haemoglobin - Hb	

Is the patient considered to be in:

- Last week of life Not in the last week of life

Charlson Comorbidity Index

- Myocardial infarction
- Congestive cardiac failure
- Peripheral vascular disease
- Cerebrovascular disease
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Ulcer disease
- Mild liver disease
- Diabetes Hemiplegia
- Moderate or severe renal disease
- Diabetes with end organ damage
- Any tumour
- Leukaemia
- Lymphoma
- Moderate or severe liver disease
- Metastatic solid tumour
- AIDS

Australian Modified Karnofsky Performance Scale (AKPS)

100	Normal; no complaints; no evidence of disease
90	Able to carry on normal activity; minor signs of symptoms
80	Normal activity with effort; some signs of symptoms or disease
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most of his needs
50	Requires considerable assistance and frequent medical care
40	In bed more than 50% of the time
30	Almost completely bedfast
20	Totally bedfast and requiring extensive nursing care by professionals and/or family
10	Comatose or barely rousable
0	Dead
	Not able to determine

Baseline – T0-Medication Commencement

Date of assessment

(dd/mm/yyyy)

Richmond Agitation Sedation Scale

Score Term Description

+4	Combative	Overtly combative, violent, immediate danger to staff (e.g. throwing items) +/- attempting to get out of bed or chair
+3	Very agitated	Pulls or removes lines (e.g. IV/oxygen tubing) or catheter(s); aggressive; +/- attempting to get out of bed or chair
+2	Agitated	Frequent non-purposeful movement +/- attempting to get out of bed or chair
+1	Restless	Occasional non purposeful movement, but not aggressive or vigorous
0	Alert and calm	

-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to voice (10 seconds or longer)
-2	Light sedation	Briefly awakens with eye contact to voice (<10 seconds)
-3	Moderate sedation	Any movement (eye or body) or eye opening to voice (but no eye contact)

-4	Deep sedation	No response to voice, but any movement (eye or body) or eye opening to stimulation by light touch
-5	Not rousable	No response to voice or stimulation by light touch

Richmond Agitation Sedation Score:

What dose of Midazolam has been given at this point in time? (mgs)

Motivation /Purpose in treating?

- Patient safety
- Family concern
- Staff concern
- Patient symptoms
- Other

Baseline Toxicity Assessment. Please grade all symptoms accordingly.

Amnesia

- 1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Confusion

- 1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Fall

- 1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
3. Hospitalization indicated

Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; oedema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalization not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Sleep apnoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Snoring and nocturnal sleep arousal without apnoeic periods
2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL
3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self-care ADL
4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

T1 – 1 hour after Baseline

T1: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

Date of Death

(dd/mm/yyyy)

End Survey here

Date and time of Assessment

D-M-Y H-M

Richmond Agitation Sedation Scale: Score Term Description

+4	Combative	Overtly combative, violent, immediate danger to staff (e.g. throwing items) +/- attempting to get out of bed or chair
+3	Very agitated	Pulls or removes lines (e.g. IV/oxygen tubing) or catheter(s); aggressive; +/- attempting to get out of bed or chair
+2	Agitated	Frequent non-purposeful movement +/- attempting to get out of bed or chair
+1	Restless	Occasional non purposeful movement, but not aggressive or vigorous
0	Alert and calm	

-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to voice (10 seconds or longer)
-2	Light sedation	Briefly awakens with eye contact to voice (<10 seconds)
-3	Moderate sedation	Any movement (eye or body) or eye opening to voice (but no eye contact)

-4	Deep sedation	No response to voice, but any movement (eye or body) or eye opening to stimulation by light touch
-5	Not rousable	No response to voice or stimulation by light touch

Richmond Agitation Sedation Score:

Total dose of Midazolam given in the past hour (including baseline)? (mgs)

Based on your assessment at this time was there any benefit?

Yes No Don't know

Medication changes

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased
- Medication of interest ceased
- New medication added

Please specify new medication here

Please specify new dose here

Toxicity assessment (T1) Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

- 1. Mild; transient memory loss
- 2. Moderate; short term memory loss; limiting instrumental ADL
- 3. Severe; long term memory loss; limiting self-care ADL

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1. Mild disorientation
- 2. Moderate disorientation; limiting instrumental ADL
- 3. Severe disorientation; limiting self-care ADL
- 4. Life-threatening consequences; urgent intervention indicated
- 5. Death

Fall

1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
3. Hospitalization indicated

Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; oedema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalization not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Sleep apnoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Snoring and nocturnal sleep arousal without apnoeic periods
2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL
3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self-care ADL
4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

- 1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

1. Did the adverse reaction appear after the suspected drug was given?
 - Yes
 - No
 - Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
 - Yes
 - No
 - Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
 - Yes
 - No
 - Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
 - Yes
 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know

T2 – 4 hours after baseline

T2: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

Date of Death

dd/mm/yyyy

End Survey here

Date and time of Assessment

D-M-Y H-M.

Richmond Agitation Sedation Scale:

Score Term Description

+4	Combative	Overtly combative, violent, immediate danger to staff (e.g. throwing items) +/- attempting to get out of bed or chair
+3	Very agitated	Pulls or removes lines (e.g. IV/oxygen tubing) or catheter(s); aggressive; +/- attempting to get out of bed or chair
+2	Agitated	Frequent non-purposeful movement +/- attempting to get out of bed or chair
+1	Restless	Occasional non purposeful movement, but not aggressive or vigorous
0	Alert and calm	

-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to voice (10 seconds or longer)
-2	Light sedation	Briefly awakens with eye contact to voice (<10 seconds)
-3	Moderate sedation	Any movement (eye or body) or eye opening to voice (but no eye contact)

-4	Deep sedation	No response to voice, but any movement (eye or body) or eye opening to stimulation by light touch
-5	Not rousable	No response to voice or stimulation by light touch

Richmond Agitation Sedation Score:

Total dose of Midazolam given in the past 4 hours (including baseline)? (mgs)

Based on your assessment at this time was there any benefit?

Yes No Don't know

Medication changes

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased
- Medication of interest ceased
- New medication added

Please specify new medication here

Please specify new dose here

Toxicity assessment (T2) Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Fall

1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
3. Hospitalization indicated

Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; oedema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalization not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Sleep apnoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Snoring and nocturnal sleep arousal without apnoeic periods
2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL
3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self-care ADL
4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

1. Did the adverse reaction appear after the suspected drug was given?
 - Yes
 - No
 - Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
 - Yes
 - No
 - Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
 - Yes
 - No
 - Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
 - Yes
 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know

T3 – 24 hours after baseline

T3: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

Date of Death

dd/mm/yyyy

End Survey here

Date and time of Assessment

D-M-Y H-M.

Richmond Agitation Sedation Scale:

Score Term Description

+4	Combative	Overtly combative, violent, immediate danger to staff (e.g. throwing items) +/- attempting to get out of bed or chair
+3	Very agitated	Pulls or removes lines (e.g. IV/oxygen tubing) or catheter(s); aggressive; +/- attempting to get out of bed or chair
+2	Agitated	Frequent non-purposeful movement +/- attempting to get out of bed or chair
+1	Restless	Occasional non purposeful movement, but not aggressive or vigorous
0	Alert and calm	

-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to voice (10 seconds or longer)
-2	Light sedation	Briefly awakens with eye contact to voice (<10 seconds)
-3	Moderate sedation	Any movement (eye or body) or eye opening to voice (but no eye contact)

-4	Deep sedation	No response to voice, but any movement (eye or body) or eye opening to stimulation by light touch
-5	Not rousable	No response to voice or stimulation by light touch

Richmond Agitation Sedation Score:

Total dose of Midazolam given in the past 24 hours (including baseline)? (mgs)

Based on your assessment at this time was there any benefit?

Yes No Don't know

Medication changes

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased
- Medication of interest ceased
- New medication added

Please specify new medication here

Please specify new dose here

Toxicity assessment (T3) Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Fall

1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
3. Hospitalization indicated

Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; oedema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalization not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Sleep apnoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Snoring and nocturnal sleep arousal without apnoeic periods
2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL
3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self-care ADL
4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

1. Did the adverse reaction appear after the suspected drug was given?
 - Yes
 - No
 - Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
 - Yes
 - No
 - Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
 - Yes
 - No
 - Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
 - Yes
 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know

Medication Cessation (complete this page at any time the medication of interest is ceased)

Date of assessment

(dd/mm/yyyy)

Medication was ceased (related to indication of interest):

- Symptom resolved
- Symptom continued unchanged
- Symptom worsened
- Symptom resolved - date of resolution

(dd/mm/yyyy)

- Symptom worsened - Grade (NCI) _____

Medication was ceased (related to other reasons):

- Toxicity
- Patient unable to take medication
- Other

Please specify the other reason medication was ceased

Please specify the patient's inability to take medication

What treatment did you subsequently initiate following cessation of the medication of interest?

Adhoc A

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

(dd/mm/yyyy)

Toxicity assessment. Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Fall

1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
3. Hospitalization indicated

Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; oedema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
3. Severe agitation; hospitalization not indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Sleep apnoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Snoring and nocturnal sleep arousal without apnoeic periods
2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL
3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self-care ADL
4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

1. Did the adverse reaction appear after the suspected drug was given?
 - Yes
 - No
 - Don't know

2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?
 - Yes
 - No
 - Don't know

3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
 - Yes
 - No
 - Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
 - Yes
 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know

Adhoc b

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

(dd/mm/yyyy)

Toxicity assessment. Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild; transient memory loss
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL

Confusion

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Fall

1 2 3 Ungradable No Symptom

NCI Criteria-

1. Minor with no resultant injuries; intervention not indicated
2. Symptomatic; non-invasive intervention indicated
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Injection site reaction

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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5. Death

Paradoxical agitation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild mood alteration
2. Moderate mood alteration
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Sleep apnoea

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4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated
5. Death

Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

- Amnesia
- Confusion
- Fall
- Injection site reaction
- Paradoxical agitation
- Sleep apnoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

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3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
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4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
 - Yes
 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know

Adhoc c

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

(dd/mm/yyyy)

Toxicity assessment. Please select all toxicities that were present and grade accordingly.

Amnesia

1 2 3 Ungradable No Symptom

NCI Criteria

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Confusion

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Fall

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NCI Criteria-

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Other (if exists)

Please specify other toxicity here _____

Other toxicity grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other toxicity here _____

Additional other toxicity grade here

1 2 3 4 5 Ungradable

Which adverse event is the most troublesome?

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 - No
 - Don't know

5. Was the adverse event confirmed by any objective evidence?
 - Yes
 - No
 - Don't know