

Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Dexamethasone for Fatigue – Series 30

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)

T0 - Baseline

Demographics

Gender Male Female Other

| | |
|-------------------|--|
| Age (yrs.) | |
|-------------------|--|

| | |
|--------------------|--|
| 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.

Charlson Comorbidity Index

- Myocardial infarction (history, not ECG changes only)
- Congestive cardiac failure
- Peripheral vascular disease (includes aortic aneurysm ≥ 6 cm)
- Cerebrovascular disease (CVA with mild or no residual or TIA)
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Peptic ulcer disease
- Mild liver disease (without portal hypertension, includes chronic hepatitis)
- Moderate or severe renal disease
- Hemiplegia
- Diabetes with end organ damage
- Diabetes (without organ damage) (excludes diet-controlled alone)
- Any tumour without metastasis (exclude if > 5 y from diagnosis)
- Leukaemia (acute or chronic)
- Lymphoma
- Moderate or severe liver disease
- Metastatic solid tumour
- AIDS (not just HIV positive)

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 |

Laboratory Tests (in last 28 days only if available)

| Test | Value |
|-------------------------------------|--------------|
| C-Reactive Protein (CRP) | |
| eGFR mL/min | |
| Blood sugar level (mmol/L or mg/dL) | |
| Haemoglobin (Hb) g/L | |
| TSH (mIU/L) | |
| Free T4 (ng/dL) | |

To Baseline – Medication Commencement

Date of assessment

| |
|------------|
| dd/mm/yyyy |
|------------|

Time of Assessment (24hr clock)

| |
|--|
| |
|--|

Symptom Severity

Fatigue

1 2 3

| |
|---|
| <i>NCI Criteria</i> 1. Fatigue relieved by rest 2. Fatigue not relieved by rest; limiting instrumental ADL 3. Fatigue not relieved by rest, limiting self-care ADL |
|---|

FATIGUE SEVERITY SCALE (FSS) Please mark an "X" on the number line which describes the patients global fatigue with 0 being worst and 10 being normal.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

Symptom Assessment Scale for fatigue

Please mark an "X" on the number line to indicate patient's level of distress

0 = you have no distress caused by the symptom.

10 = means you are experiencing the worst possible distress caused by the symptom

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

Dexamethasone starting dose:

| | |
|--|--|
| Dose (mgs) | |
| Frequency: e.g. Daily (mane), BD, TDS, QID | |
| Route: oral, subcutaneous | |

Is patient currently on or being commenced on gastric protection e.g. ranitidine or esomeprazole?

Yes No

Baseline Symptom/Harm Assessment

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

| |
|---|
| <i>NCI Criteria</i> 1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L 2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L 3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization Indicated 4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences 5. Death |
|---|

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Depression

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Insomnia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Delirium

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

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

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

Other (if exists – e.g. fluid retention)

Please specify other harm here _____

Other harm grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other harm here _____

Additional other harm grade here

1 2 3 4 5 Ungradable

Which harm is the most troublesome?

- Hyperglycaemia
- Mania
- Depression
- Insomnia
- Delirium
- Agitation
- Dyspepsia
- Increased Appetite
- Other
- Additional Other
- Not applicable

T1- 5-7days post baseline

T₁: Assessed/Not assessed reason

- Assessed today (continue to complete T₁) OR
- Died
- Not able to be contacted / located
- Too unwell
- Other

Date of Death

(dd/mm/yyyy)

End Survey here

Date and time of assessment

| | |
|-------------------|--|
| dd/mm/yyyy | |
| 24hr time | |

Target Symptom Severity

Fatigue

- 1
- 2
- 3

NCI Criteria

1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rest, limiting self-care ADL

FATIGUE SEVERITY SCALE (FSS) Please mark an "X" on the number line which describes the patients global fatigue with 0 being worst and 10 being normal.

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

Symptom Assessment Scale for fatigue (SAS)

Please mark an "X" on the number line to indicate patient's level of distress

0 = means you have no distress caused by the symptom.

10 = means you are experiencing the worst possible distress caused by the symptom

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

Dexamethasone current dose:

| | |
|-------------------------------------|--|
| Dose (mgs) | |
| Frequency: e.g. Daily, BD, TDS, QID | |
| Route: oral, subcutaneous | |

Baseline Symptom/Harm Assessment

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization Indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Depression

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Insomnia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Delirium

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

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

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

Other (if exists– e.g. fluid retention)

Please specify other harm here _____

Other harm grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other harm here _____

Additional other harm grade here

1 2 3 4 5 Ungradable

Which harm is the most troublesome?

- Hyperglycaemia
- Mania
- Depression
- Insomnia
- Delirium
- Agitation
- Dyspepsia
- Increased Appetite
- Other
- Additional Other
- Not applicable

Key questions derived from the Naranjo modified check list (only complete if a harm symptom scores 3 or more)

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

What is the intended treatment based on today's assessment?

- No change to dexamethasone continue current dose
- Dexamethasone ceased
- Dexamethasone reduced

| | |
|---------------------------------|--|
| What is the reduced dose? (mgs) | |
|---------------------------------|--|

Reason dexamethasone reduced (tick all that apply)

- Weaning off dexamethasone
- Routine practice
- Side effects
- Other (please specify): _____

- Dexamethasone dose increased – please specify dose

What is the increased dose? (mgs) _____

Has a medication been added to treat a specific harm?

Yes No

If yes please specify medication.

| |
|--|
| |
|--|

Based on the assessment today has the harm resolved?

Yes No N/A

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 worsened (please grade below)
- Symptom continued unchanged

Medication was ceased (related to other reasons):

- Toxicity/harm
- Patient unable to take medication
- Other

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

Symptom resolved – date of resolution

dd/mm/yyyy

Symptom worsened

- 1 2 3 ungradable

NCI Criteria

1. Fatigue relieved by rest
2. Fatigue not relieved by rest; limiting instrumental ADL
3. Fatigue not relieved by rest, limiting self-care ADL

Please specify the 'other' reason medication was ceased

Please specify the patient's inability to take medication

Adhoc A- Unscheduled Adverse Event/Harm Assessment

Please complete the survey below.

Were there any adhoc adverse events/harms?

Yes No

Date of assessment

Adverse event/Harm Assessment.

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization Indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Depression

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Insomnia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Delirium

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

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

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

Other (if exists)

Please specify other harm here _____

Other harm grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other harm here _____

Additional other harm grade here

1 2 3 4 5 Ungradable

Which harm is the most troublesome?

- Hyperglycaemia
- Mania
- Depression
- Insomnia
- Delirium
- Agitation
- Dyspepsia
- Increased Appetite
- Other
- Additional Other

Key questions derived from the Naranjo modified check list (only complete if a harm symptom scores 3 or more)

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

Ahoc B- Unscheduled Adverse Event/Harm Assessment

Please complete the survey below.

Were there any adhoc adverse events/harms?

Yes No

Date of assessment

Adverse event/Harm Assessment.

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization Indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Depression

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Insomnia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Delirium

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

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

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

Other (if exists)

Please specify other harm here _____

Other harm grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other harm here _____

Additional other harm grade here

1 2 3 4 5 Ungradable

Which harm is the most troublesome?

- Hyperglycaemia
- Mania
- Depression
- Insomnia
- Delirium
- Agitation
- Dyspepsia
- Increased Appetite
- Other
- Additional Other

Key questions derived from the Naranjo modified check list (only complete if a harm symptom scores 3 or more)

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 C- Unscheduled Adverse Event/Harm Assessment

Please complete the survey below.

Were there any adhoc adverse events/harms?

Yes No

Date of assessment

Adverse event/Harm Assessment.

Hyperglycaemia

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
2. Fasting glucose value >160 - 250 mg/dL; Fasting glucose value >8.9 - 13.9 mmol/L
3. >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization Indicated
4. >500 mg/dL; >27.8 mmol/L; life-threatening consequences
5. Death

Mania

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild manic symptoms (e.g., elevated mood, rapid thoughts, rapid speech, decreased need for sleep)
2. Moderate manic symptoms (e.g., relationship and work difficulties; poor hygiene)
3. Severe manic symptoms (e.g., hypomania; major sexual or financial indiscretions); hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Depression

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild depressive symptoms
2. Moderate depressive symptoms; limiting instrumental ADL
3. Severe depressive symptoms; limiting self-care ADL; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

Insomnia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild difficulty falling asleep, staying asleep or waking up early
2. Moderate difficulty falling asleep, staying asleep or waking up early
3. Severe difficulty in falling asleep, staying asleep

Delirium

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild acute confusional state
2. Moderate and acute confusional state; limiting instrumental ADL
3. Severe and acute confusional state; limiting self-care ADL; hospitalization indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

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

Dyspepsia

1 2 3 Ungradable No Symptom

NCI Criteria

1. Dyspepsia Mild symptoms; intervention not indicated
2. Moderate symptoms; medical intervention indicated
3. Severe symptoms; surgical intervention indicated

Increased Appetite/Weight gain

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild increase in appetite; 5-<10% increase in weight from baseline
2. Moderate increase in appetite; 10-<20% increase in weight from baseline
3. Extreme increase in appetite; >20% increase in weight from baseline

Other (if exists)

Please specify other harm here _____

Other harm grade here:

1 2 3 4 5 Ungradable

Additional other (if exists)

Please specify additional other harm here _____

Additional other harm grade here

1 2 3 4 5 Ungradable

Which harm is the most troublesome?

- Hyperglycaemia
- Mania
- Depression
- Insomnia
- Delirium
- Agitation
- Dyspepsia
- Increased Appetite
- Other
- Additional Other

Key questions derived from the Naranjo modified check list (only complete if a harm symptom scores 3 or more)

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