

Participant ID (PID)

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Cyclizine (NAUSEA/VOMITING) Series No: 12

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)

Cyclizine for Nausea/Vomiting - Baseline

Demographics

Gender Male
 Female

Age _____

Weight (kg)	
Height (cm)	

Primary life limiting illness

- Advanced metastatic 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

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

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.

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.

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

Charlson Comorbidity Index

- Myocardial infarction
- Congestive cardiac failure
- Peripheral vascular disease
- Cerebrovascular disease
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Peptic 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 (dd/mm/yyyy)

Indication of interest

Nausea Vomiting

Nausea

0 1 2 3

NCI Criteria

0. Nil
1. loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

Vomiting

0 1 2 3 4 5

NCI Criteria

0. Nil
1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hour
3. >=6 episodes (separated by > 5 minutes) in 24 hours; tube feeding, TPN or hospitalization indicated
4. life threatening consequences; urgent intervention indicated
5. Death

Dominant mechanism of nausea - choose one

- Central / CTZ stimulation
- CNS disease
- Vestibular involvement
- Ileus
- Gastritis
- Gastric stasis
- Cause undetermined (or multifactorial)
- Mechanical obstruction

Current other antiemetics – choose all that apply

- Metoclopramide
- Haloperidol
- Ondansetron
- Levomepromazine
- Steroids
- Other

Please specify Other Antiemetic here:

Commencement dose of Cyclizine (mg)

Route of administration Oral Injectable Both

Frequency of administration:

- QID (6th hrly) TDS (8th hrly) BD (12hrly)
 Other-please specify (e.g. PRN):_____

Baseline - Toxicity assessment

Please select all symptoms that were present at assessment.

Dry mouth

- 1 2 3 Ungradable No Symptom

NCI Criteria

1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

Dizziness

- 1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

Blurred vision

- 1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

Palpitations

- 1 2 Ungradable No Symptom

NCI Criteria

1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

Somnolence

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

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

Constipation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Urinary retention

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

Seizures

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

Extrapyramidal disorder

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Heart failure

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities
2. Symptoms with mild to moderate activity or exertion
3. Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4. Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical haemodynamic support)
5. Death

Respiratory secretions

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

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; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent 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 toxicity is the most troublesome?

- Dry Mouth
- Blurred vision
- Constipation
- Urinary retention
- Confusion
- Dizziness
- Somnolence
- Seizures
- Extrapiramidal disorder
- Heart failure
- Palpitations
- Respiratory secretions
- Injection site reaction
- Other 1
- Other 2

T₁ - 72 hours 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 of Assessment

(dd/mm/yyyy)

If today's date of assessment is not three days after the Baseline date of assessment please provide the reason below

Indication of interest

Nausea Vomiting

Nausea

- 0 1 2 3

NCI Criteria

0. Nil

1. loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

Vomiting

- 0 1 2 3 4 5

NCI Criteria

0. Nil

1. 1-2 episodes (separated by > 5 minutes) in 24 hours
2. 3-5 episodes (separated by > 5 minutes) in 24 hour
3. >=6 episodes (separated by > 5 minutes) in 24 hours; tube feeding, TPN or hospitalization indicated
4. life threatening consequences; urgent intervention indicated
5. Death

Total dose of Cyclizine given in the last 24 hours (mg)

How long has the patient been on this dose (days)

Route of administration: Oral Injectable Both

Frequency of administration:

- QID (6th hrly) TDS (8th hrly) BD (12hrly)
 Other-please specify (e.g. PRN):_____

Was there any benefit?

Yes . No

Current other antiemetics

- Metoclopramide
- Haloperidol
- Ondansetron
- Levomepromazine
- Steroids
- Other

Please specify Other Antiemetic here: _____

What response was taken?

- Cyclizine dose unchanged
- Cyclizine dose decreased
- Cyclizine dose increased –specify below
- Cyclizine ceased
- New medication added – specify below
- Other

Please specify the 'Other' response taken here:

Please specify new medication added here

Please specify new dose of Cyclizine here

Frequency of new dose of Cyclizine:

- QID (6th hrly) TDS (8th hrly) BD (12hrly) Other-please specify:_____

Toxicity assessment (T₁) Please select all symptoms that were present at assessment.

Dry mouth

1 2 3 Ungradable No Symptom

NCI Criteria

1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

Palpitations

1 2 Ungradable No Symptom

NCI Criteria

1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

Somnolence

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

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

Constipation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Urinary retention

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

Seizures

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

Extrapyramidal disorder

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Heart failure

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities
2. Symptoms with mild to moderate activity or exertion
3. Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4. Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical haemodynamic support)
5. Death

Respiratory secretions

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

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; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent 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 toxicity is the most troublesome?

- Dry Mouth
- Blurred vision
- Constipation
- Urinary retention
- Confusion
- Dizziness
- Somnolence
- Seizures
- Extrapyrimal disorder
- Heart failure
- Palpitations
- Respiratory secretions
- Injection site reaction
- Other 1
- Other 2

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

Adhoc Toxicities A - Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

dd/mm/yyyy	
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Was there any benefit?

Yes No

What is the intended treatment based on the assessment today?

- No change to Cyclizine / continue current dose
- Cyclizine dose reduced
- Cyclizine ceased
- Medication to treat a specific toxicity added
- Cyclizine dose increased (please specify new dose)

Please specify new medication here

--

Specify new dose of Cyclizine here (mgs)

--

Dry mouth

1 2 3 Ungradable No Symptom

NCI Criteria

1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

Palpitations

1 2 Ungradable No Symptom

NCI Criteria

1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

Somnolence

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

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

Constipation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Urinary retention

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

Seizures

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

Extrapyramidal disorder

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Heart failure

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities
2. Symptoms with mild to moderate activity or exertion
3. Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4. Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical haemodynamic support)
5. Death

Respiratory secretions

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

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; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent 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 toxicity is the most troublesome?

- Dry Mouth
- Blurred vision
- Constipation
- Urinary retention
- Confusion
- Dizziness
- Somnolence
- Seizures
- Extrapyrarnidal disorder
- Heart failure
- Palpitations
- Respiratory secretions
- Injection site reaction
- Other 1
- Other 2

Key questions derived from the Naranjo modified check list

***If there was a harm given a grade of 3 or more, please complete the Naranjo Checklist for the most troublesome harm.**

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

For Quality improvement purposes: Did you complete this survey on a mobile platform or computer platform?

- Mobile
- Computer

Adhoc Toxicities B - Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

dd/mm/yyyy	
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Was there any benefit?

Yes No

What is the intended treatment based on the assessment today?

- No change to Cyclizine / continue current dose
- Cyclizine dose reduced
- Cyclizine ceased
- Medication to treat a specific toxicity added
- Cyclizine dose increased (please specify new dose)

Please specify new medication here

--

Specify new dose of Cyclizine here (mgs)

--

Dry mouth

1 2 3 Ungradable No Symptom

NCI Criteria

1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

Palpitations

1 2 Ungradable No Symptom

NCI Criteria

1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

Somnolence

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

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

Constipation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Urinary retention

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

Seizures

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

Extrapyramidal disorder

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Heart failure

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities
2. Symptoms with mild to moderate activity or exertion
3. Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4. Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical haemodynamic support)
5. Death

Respiratory secretions

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

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; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent 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 toxicity is the most troublesome?

- Dry Mouth
- Blurred vision
- Constipation
- Urinary retention
- Confusion
- Dizziness
- Somnolence
- Seizures
- Extrapyrarnidal disorder
- Heart failure
- Palpitations
- Respiratory secretions
- Injection site reaction
- Other 1
- Other 2

Key questions derived from the Naranjo modified check list

***If there was a harm given a grade of 3 or more, please complete the Naranjo Checklist for the most troublesome harm.**

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 Toxicities C - Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment

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

Was there any benefit?

Yes No

What is the intended treatment based on the assessment today?

- No change to Cyclizine / continue current dose
- Cyclizine dose reduced
- Cyclizine ceased
- Medication to treat a specific toxicity added
- Cyclizine dose increased (please specify new dose)

Please specify new medication here

--

Specify new dose of Cyclizine here (mgs)

--

Dry mouth

1 2 3 Ungradable No Symptom

NCI Criteria

1. Symptomatic (dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min
2. Symptomatic and significant oral intake alteration (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min
3. Symptoms leading to inability to adequately aliment orally; IV fluids, tube feedings, or TPN indicated; unstimulated saliva < 0.1 ml/min

Dizziness

1 2 3 Ungradable No Symptom

NCI Criteria

1. Mild unsteadiness or sensation of movement
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3. Severe unsteadiness or sensation of movement; limiting self-care ADL

Blurred vision

1 2 3 Ungradable No Symptom

NCI Criteria

1. Intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Limiting self-care ADL

Palpitations

1 2 Ungradable No Symptom

NCI Criteria

1. Present with associated symptoms (e.g., lightheadedness)
2. Shortness of breath

Somnolence

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

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

Constipation

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

Urinary retention

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
4. Life-threatening consequences; organ failure; urgent operative intervention indicated
5. Death

Seizures

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Brief partial seizure; no loss of consciousness
2. Brief generalized seizure
3. Multiple seizures despite medical intervention
4. Life-threatening; prolonged repetitive seizures
5. Death

Extrapyramidal disorder

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Heart failure

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Asymptomatic with laboratory (e.g., BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities
2. Symptoms with mild to moderate activity or exertion
3. Severe with symptoms at rest or with minimal activity or exertion; intervention indicated
4. Life-threatening consequences; urgent intervention indicated (e.g., continuous IV therapy or mechanical haemodynamic support)
5. Death

Respiratory secretions

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Mild or asymptomatic symptoms; clinical or diagnostic observation only; intervention not indicated
2. Moderate, minimal, local or noninvasive intervention indicated; limiting age appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening, hospitalisation or prolongation of hospitalisation indicated; disabling, limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

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; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent 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 toxicity is the most troublesome?

- Dry Mouth
- Blurred vision
- Constipation
- Urinary retention
- Confusion
- Dizziness
- Somnolence
- Seizures
- Extrapiramidal disorder
- Heart failure
- Palpitations
- Respiratory secretions
- Injection site reaction
- Other 1
- Other 2

Key questions derived from the Naranjo modified check list

***If there was a harm given a grade of 3 or more, please complete the Naranjo Checklist for the most troublesome harm.**

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