

Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

**Mirtazapine (for Anorexia) Series 14**

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)

## Mirtazapine for Anorexia - 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

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	

**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

### Target Symptom

#### Anorexia

0    1    2    3    4    5

#### *NCI Criteria:*

##### Anorexia

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

### Non target symptom benefit

#### Mood

0    1    2    3    4    5    ungradable    no symptom

#### *NCI Criteria- Mood*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

**Sleep**

0    1    2    3    ungradable    no symptom

*NCI Criteria – Insomnia*

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 or waking up early

**If available please specify patient's current weight (kg)**

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

**Lethargy (grade either 1 or 2)**

1    2    Ungradable    No Symptom

*NCI Criteria-Lethargy*

1. Mild symptoms; reduced alertness and awareness
2. Moderate symptoms; limiting instrumental ADL

**Headache**

1    2    3    Ungradable    No Symptom

*NCI Criteria-Headache*

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

**Dizziness**

1    2    3    Ungradable    No Symptom

*NCI Criteria- Dizziness*

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

**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

**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?

- Lethargy
- Headache
- Dizziness
- Somnolence
- Other 1
- Other 2

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

Mobile   
Computer

## T1 – 7 days post 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 of Assessment Today

dd/mm/yyyy

Please provide reason why if today's date of assessment is not three days after Baselines date of assessment.

### Anorexia

- 0    1    2    3    4    5

*NCI Criteria:*

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

### Non target symptom benefit

#### Mood

- 0    1    2    3    4    5    ungradable    no symptom

*NCI Criteria-*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

**Sleep**

0    1    2    3    4    5    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 or waking up early

**Actual weight of patient if available (kg)**

With no available weight the clinical impression is?

- Weight stable
- Weight loss
- Weight gain
- Unsure

**Total dose given in the last 24 hours (mg)** \_\_\_\_\_

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

**Was there any benefit?**

Yes

No

Please describe benefit in a few words

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 symptoms that were present at assessment.**

**Lethargy (grade either 1 or 2)**

1    2    Ungradable    No Symptom

NCI Criteria-Lethargy  
3. Mild symptoms; reduced alertness and awareness  
4. Moderate symptoms; limiting instrumental ADL

**Headache**

1    2    3    Ungradable    No Symptom

NCI Criteria-Headache  
1. Mild pain  
2. Moderate pain; limiting instrumental ADL  
3. Severe pain; limiting self-care ADL

**Dizziness**

1    2    3    Ungradable    No Symptom

NCI Criteria- Dizziness  
1. Mild unsteadiness or sensation of movement  
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL  
3. Severe unsteadiness or sensation of movement

**Somnolence**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria  
6. Mild but more than usual drowsiness or sleepiness  
7. Moderate sedation; limiting instrumental ADL  
8. Obtundation or stupor  
9. Life-threatening consequences; urgent intervention indicated  
10. 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?

- Lethargy  
 Headache  
 Dizziness  
 Somnolence  
 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

### Toxicity assessment follow-up

What is the intended treatment based on the assessment today?

- No change to medication of interest/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased
- Medication of interest ceased

Has a medication been added to treat a specific toxicity?

- Yes
- No

Please specify medication to treat toxicity

## T2 – Day 14 assessment

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 of Assessment Today

dd/mm/yyyy

Please provide reason why if today's date of assessment is not three days after Baselines date of assessment.

### Anorexia

- 0    1    2    3    4    5

*NCI Criteria:*

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

### Non target symptom benefit

#### Mood

- 0    1    2    3    4    5    ungradable    no symptom

*NCI Criteria-*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

**Sleep**

0    1    2    3    4    5    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 or waking up early

**Actual weight of patient if available (kg)**

With no available weight the clinical impression is?

- Weight stable
- Weight loss
- Weight gain
- Unsure

**Total dose given in the last 24 hours (mg)** \_\_\_\_\_

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

**Was there any benefit?**

Yes

No

Please describe benefit in a few words

**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 (mgs)

**Toxicity assessment (T2) Please select all symptoms that were present at assessment.**

**Lethargy (grade either 1 or 2)**

1    2    Ungradable    No Symptom

NCI Criteria-Lethargy  
5. Mild symptoms; reduced alertness and awareness  
6. Moderate symptoms; limiting instrumental ADL

**Headache**

1    2    3    Ungradable    No Symptom

NCI Criteria-Headache  
1. Mild pain  
2. Moderate pain; limiting instrumental ADL  
3. Severe pain; limiting self-care ADL

**Dizziness**

1    2    3    Ungradable    No Symptom

NCI Criteria- Dizziness  
1. Mild unsteadiness or sensation of movement  
2. Moderate unsteadiness or sensation of movement; limiting instrumental ADL  
3. Severe unsteadiness or sensation of movement

**Somnolence**

1    2    3    4    5    Ungradable    No Symptom

NCI Criteria  
11. Mild but more than usual drowsiness or sleepiness  
12. Moderate sedation; limiting instrumental ADL  
13. Obtundation or stupor  
14. Life-threatening consequences; urgent intervention indicated  
15. 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?

- Lethargy
- Headache
- Dizziness
- Somnolence
- Other 1
- Other 2

**Key questions derived from the Naranjo modified check list**

6. Did the adverse reaction appear after the suspected drug was given?

- Yes
- No
- Don't know

7. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?

- Yes
- No
- Don't know

8. Are there alternative causes (other than the drug) that could on their own have caused the reaction?

- Yes
- No
- Don't know

9. Did the patient have a similar reaction to the same or similar drug in any previous exposure?

- Yes
- No
- Don't know

10. Was the adverse event confirmed by any objective evidence?

- Yes
- No
- Don't know

### Toxicity assessment follow-up

What is the intended treatment based on the assessment today?

- No change to medication of interest/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased
- Medication of interest ceased

Has a medication been added to treat a specific toxicity?

- Yes
- No

Please specify medication to treat toxicity



**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

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Please specify the patient's inability to take medication

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## Adhoc A

Please complete the survey below.

Were there any adhoc toxicities?

Yes  No

### Date of assessment

### Anorexia

0  1  2  3  4  5

#### *NCI Criteria:*

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

### Non target symptom

#### Mood

0  1  2  3  4  5  ungradable  no symptom

#### *NCI Criteria*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

#### Sleep

0  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 or waking up early

Was there any benefit?

Yes  
 No

What is the intended treatment based on the assessment today?

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

Please specify new medication here

---

Specify new dose here

---

## Toxicities

**Lethargy (grade either 1 or 2)**

- 1    2    Ungradable    No Symptom

*NCI Criteria*

1. Mild symptoms; reduced alertness and awareness
2. Moderate symptoms; limiting instrumental ADL

**Headache**

- 1    2    3    Ungradable    No Symptom

*NCI Criteria*

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

**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

**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

**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?

- Lethargy
- Headache
- Dizziness
- Somnolence
- Other 1
- Other 2

## Adhoc b

Please complete the survey below.

Were there any adhoc toxicities?

Yes  No

## Date of assessment

## Anorexia

0  1  2  3  4  5

### *NCI Criteria:*

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

## Non target symptom

### Mood

0  1  2  3  4  5  ungradable  no symptom

### *NCI Criteria*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

### Sleep

0  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 or waking up early

Was there any benefit?

Yes  
 No

What is the intended treatment based on the assessment today?

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

Please specify new medication here

---

Specify new dose here

---

### Toxicities

**Lethargy (grade either 1 or 2)**

- 1     2     Ungradable     No Symptom

*NCI Criteria*

1. Mild symptoms; reduced alertness and awareness
2. Moderate symptoms; limiting instrumental ADL

**Headache**

- 1     2     3     Ungradable     No Symptom

*NCI Criteria*

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

**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

**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

**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?

- Lethargy
- Headache
- Dizziness
- Somnolence
- Other 1
- Other 2

### Adhoc c

Please complete the survey below.

Were there any adhoc toxicities?

Yes  No

Date of assessment

### Anorexia

0  1  2  3  4  5

*NCI Criteria:*

1. Loss of appetite without alteration in eating habits
2. Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated
3. Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

### Non target symptom

#### Mood

0  1  2  3  4  5  ungradable  no symptom

*NCI Criteria*

1. Mild mood alteration
2. Moderate mood alteration
3. Severe mood alteration/hospitalisation not indicated
4. Life threatening consequences – urgent intervention required
5. Death

#### Sleep

0  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 or waking up early

Was there any benefit?

Yes  
 No



What is the intended treatment based on the assessment today?

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

Please specify new medication here

---

Specify new dose here

---

### Toxicities

**Lethargy (grade either 1 or 2)**

- 1     2     Ungradable     No Symptom

*NCI Criteria*

1. Mild symptoms; reduced alertness and awareness
2. Moderate symptoms; limiting instrumental ADL

**Headache**

- 1     2     3     Ungradable     No Symptom

*NCI Criteria*

1. Mild pain
2. Moderate pain; limiting instrumental ADL
3. Severe pain; limiting self-care ADL

**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

**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

**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?

- Lethargy
- Headache
- Dizziness
- Somnolence
- Other 1
- Other 2