

Participant ID

Initials of person entering data

Staff email

CONFIDENTIAL CASE REPORT FORM

Movicol/Macrogol Series 11

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)

Movicol/Macrogol – Baseline (T0)

Demographics

Does this patient have a bowel obstruction?

- No Yes (patient excluded)

- Gender** Male
 Female

Age (yrs)

Weight (kg)		Pt reported <input type="checkbox"/>
Height (cm)		Pt reported <input type="checkbox"/>

Primary life limiting illness

- Advanced 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.

Current place of care

- Inpatient
- Outpatient
- Other

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 Assessment (To)

Date of assessment (dd/mm/yyyy)

Dosing details

Specify product (e.g. Clearlax, Osmolax, Movicol)	
Time of last dose (in 24 hr clock (e.g. 2200))	
Dose regimen (e.g. 1 sachet BD)	

What constipation symptoms is the patient experiencing that has led to the prescribing of this medication? (choose one only)

- Infrequent bowel actions
- Straining to pass bowel actions
- Dissatisfaction in current bowel habits
- Passing small or hard stools
- Abdominal pain or discomfort
- Abdominal bloating

What is the underlying mechanism of constipation symptoms in the opinion of the care team?

Functional

Constipation for which there is no obvious physical, biochemical or iatrogenic causes for

Medication induced

(please specify below)

Analgesics (e.g. opioids)
Psychiatric Antidepressants:
tricyclics (e.g. amitriptyline, dothiepin)
MAOIs (e.g. phenelzine)
SSRIs (e.g. fluoxetine, paroxetine)
Antipsychotics
Endocrine:
Pamidronate, alendronate, bromocriptine
Gastroenterological:
Proton pump inhibitors (e.g. omeprazole)
Others including pancreatin, 5-ASA compounds, octreotide
Cardiac:
ACE inhibitors (e.g. captopril, lisinopril)
Calcium-channel blockers (e.g. nifedipine, verapamil)
Anti-arrhythmics (e.g. amiodarone, flecainide)
Lipid-lowering agents (e.g. atorvastatin, cholestyramine)

Antihypertensives (e.g. acebutolol, clonidine)
Haematological/oncological:
Erythropoietin, carboplatin, vinblastine
Neurological:
Anti-epileptics (e.g. carbamazepine, sodium valproate)
Muscle relaxants (e.g. baclofen)
Pituitary suppression (e.g. bromocriptine)
Parkinson's disease (e.g. pergolide)
Miscellaneous:
Antimuscarinics (e.g. hyoscine, atropine)
Nicotine
Ondansetron

Metabolic

Hypothyroid
Hypercalcaemia

Neurological

Autonomic neuropathy
Multiple sclerosis
Parkinson's disease
Spinal cord injury

Psychological

Depression

Others

Dehydration
Poor oral intake
Reduced mobility

Please specify which medications induced symptoms here

Is patient currently taking regular opioids?

Yes No

Number of times a bowel motion has been passed in the last 7 days?

1 2 3 4 5 6 7 8 9 10 Unsure

Is the patient using Movicol/Macrogol as:

	Yes	No	Regular	PRN
First line alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
First line with other laxatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Second line alone (i.e. previous laxatives ceased and Macrogol commenced)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Second line with other laxatives (i.e. previous laxatives continued and Macrogol added)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Third line alone (i.e. previous laxatives ceased and Macrogol commenced)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Third line with other laxatives (i.e. previous laxatives continued and Macrogol added)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

What other regular laxatives are being used at this time point

Laxative 1	
Laxative 2	
Laxative 3	
Laxative 4	

Constipation Symptom Severity Score

1 2 3 4 5 Ungradable

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

Baseline Symptoms of Interest (prior to commencement of medication)

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

In addition to the GI toxicities and grading provided we would like to understand what other problems are present in the patient are being prescribed this medication at this time. Please tick any of the below items if present in the patient regardless of severity

Immune system disorders (allergic reactions)

- Anaphylactic reactions
- Dyspnoea
- Skin reactions

Skin and subcutaneous tissue disorders (allergic skin reactions)

- Angioedema
- Urticarial
- Pruritus (rash)
- Erythema

Metabolism and nutrition disorders

- Hyperkalaemia
- Hypokalaemia

Nervous system disorders

- Headache

Gastrointestinal disorders

- Abdominal pain
- Diarrhoea
- Vomiting
- Nausea
- Dyspepsia
- Abdominal distension
- Borborygmi
- Flatulence
- Anorectal discomfort

General disorders and administration site conditions

- Peripheral Oedema

T1 – 2 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

(dd/mm/yyyy)

Please provide reason why if today's date of assessment is not 2 days after Baselines date of assessment.

Dose regimen in last 24 hours (e.g. 1 sachet)

If dose was not administered please provide a reason

Number of times a bowel action has been passed in the last 2 days?

Was there any benefit

- Yes
- No

Constipation Symptom Severity Score

- 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

Symptomatic Adverse Event/Toxicity Assessment – T1 (Day 1 – Day 2) Please list any symptomatic adverse events that occur (regardless of whether they are attributable to the medication of interest or not)

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

- 1.No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

- 1.Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

- 1.Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

- 1.Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

(only complete this section if any toxicity scored 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

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 – please specify below
- No

Please specify medication to treat toxicity here

Based on the assessment today has the toxicity resolved?

- Yes
- No
- Not applicable

T2 – Day 7 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

dd/mm/yyyy

Please provide reason why if today's date of assessment is not 7 days after Baselines date of assessment.

Dose regimen in last 24 hours (e.g. 1 sachet)

If dose was not administered please provide a reason

Number of times a bowel action has been passed in the last 2 days?

Was there any benefit

- Yes
- No

Constipation Symptom Severity Score

- 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

Symptomatic Adverse Event/Toxicity Assessment – T2 (Day 3 – Day 7) Please list any symptomatic adverse events that occur (regardless of whether they are attributable to the medication of interest or not)

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

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

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

(only complete this section if any toxicity scored 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

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-please specify below
- No

Please specify medication to treat toxicity here

Based on the assessment today has the toxicity resolved?

- Yes
- No
- Not applicable

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- please specify below
- Other - please specify the other reason medication was ceased

Please specify the patient's inability to take medication

Unscheduled Adverse Event/Toxicity Assessment - Adhoc A

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment (dd/mm/yyyy)

Constipation Symptom Severity Score

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

Toxicities

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. ≥ 6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of ≥ 7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

(only complete this section if any toxicity scored 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

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

Based on the assessment today has the toxicity resolved?

- Yes
- No
- Not applicable

Unscheduled Adverse Event/Toxicity Assessment - Adhoc b

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment (dd/mm/yyyy)

Constipation Symptom Severity Score

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

Toxicities

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. ≥ 6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of ≥ 7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

(only complete this section if any toxicity scored 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

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

Based on the assessment today has the toxicity resolved?

- Yes
- No
- Not applicable

Unscheduled Adverse Event/Toxicity Assessment - Adhoc C

Please complete the survey below.

Were there any adhoc toxicities?

Yes No

Date of assessment (dd/mm/yyyy)

Constipation Symptom Severity Score

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

Toxicities

Abdominal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Nausea

1 2 3 ungradable no symptom

NCI Criteria

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

Anal Pain

1 2 3 ungradable no symptom

NCI Criteria

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

Dyspepsia

1 2 3 ungradable no symptom

NCI Criteria

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

Abdominal distension

1 2 3 ungradable no symptom

NCI Criteria

1. Asymptomatic; clinical or diagnostic observations only; intervention not indicated
2. Symptomatic; limiting instrumental ADL
3. Severe discomfort; limiting self-care ADL

Bloating (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. No change in bowel function or oral intake
2. Symptomatic, decreased oral intake; change in bowel function

Flatulence (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Mild symptoms; intervention not indicated
2. Moderate; persistent; psychosocial sequelae

Dysgeusia (only grade as 1 or 2)

1 2 ungradable no symptom

NCI Criteria

1. Altered taste but no change in diet
2. Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste

Vomiting

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. 1 - 2 episodes (separated by 5 minutes) in 24 hrs
2. 3 - 5 episodes (separated by 5 minutes) in 24 hrs
3. ≥ 6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

Diarrhoea

1 2 3 4 5 Ungradable No Symptom

NCI Criteria

1. Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
3. Increase of ≥ 7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
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?

- Abdominal pain
- Nausea
- Anal pain
- Headache
- Dyspepsia
- Abdominal Distension
- Bloating
- Flatulence
- Dysgeusia
- Vomiting
- Diarrhoea
- Other
- Additional Other

Key questions derived from the Naranjo modified check list

(only complete this section if any toxicity scored 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?
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 No
 Don't know

4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
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5. Was the adverse event confirmed by any objective evidence?
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 No
 Don't know

Toxicity assessment follow-up

What is the intended treatment based on the assessment today?

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- 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

Based on the assessment today has the toxicity resolved?

- Yes
- No
- Not applicable