Chemotherapy-Induced Nausea and Vomiting and Oral Chemotherapy Related Adverse Events

Megan May, Pharm.D., BCOP

Learning Objectives

• Identify chemotherapy induced nausea and vomiting (CINV) risk factors of patients receiving chemotherapy
• List the antiemetic therapy agents available in the treatment of CINV
• Recognize unique adverse effects associated with oral oncologics
• Discuss how to assess and select appropriate management strategies with adverse effects associated with oral oncologics
Chemotherapy-Induced Nausea and Vomiting (CINV)

- From the patient’s perspective, the two most feared adverse events in receiving treatment of cancer are nausea/vomiting (N/V) and alopecia
- 75 - 80% of patients undergoing chemotherapy experience emesis
- 10 - 44% of patients experience anticipatory emesis

Terminology

- Nausea
  - Subjective symptom
  - Perception that vomiting may occur

- Retching
  - Non-productive attempt to vomit
  - Precede or alternate with vomiting

- Vomiting
  - Objective symptom
  - Explosive expulsion of GI contents

Classification of CINV

- Acute CINV
  - Occurs within a few minutes to several hours after chemotherapy administration
  - Resolves within 24 hours

- Delayed CINV
  - Begins > 24 hours after chemotherapy administration

- Anticipatory CINV
  - Conditioned response resulting from poor emetic control with previous chemotherapy

- Breakthrough CINV
  - Occurs despite administration of antiemetics

- Refractory CINV
  - Occurs when prophylactic/breakthrough antiemetics have failed in earlier cycles

Clinical Significance

• Complications
  • Malnutrition and malabsorption
  • Electrolyte and acid/base abnormalities
  • Aspiration pneumonia
  • Depression and anxiety disorders
  • Weakness
  • Weight loss
  • Dehydration

Risk Factors

• Patient factors
  • Female gender
  • Younger age
  • History of motion sickness
  • History of N/V associated with pregnancy
  • Prior history of chemotherapy
  • Low alcohol consumption

• Treatment factors
  • Certain chemotherapy agents
  • Dosage
  • Rate of administration
  • Route of administration
  • Combinations of agents

Emetogenicity of Chemotherapy

<table>
<thead>
<tr>
<th>Emetic Risk</th>
<th>Percent of patients experiencing acute emesis without prophylaxis</th>
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</thead>
<tbody>
<tr>
<td>High</td>
<td>≥ 90%</td>
</tr>
<tr>
<td>Moderate</td>
<td>30% to 90%</td>
</tr>
<tr>
<td>Low</td>
<td>10% to 29%</td>
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<tr>
<td>Minimal</td>
<td>&lt; 10%</td>
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Principles of Emesis Control

- Goal: prevention of N/V
- Patients need to be protected throughout the full period of risk
  - 4 days for highly emetogenic chemotherapy
  - 3 days for moderately emetogenic chemotherapy
- Consider the toxicity of specific antiemetic(s)
Principles of Emesis Control

• Choose antiemetic(s) based on
  • Emetic risk of therapy
  • Prior experience with antiemetics
  • Patient factors
• For multi-drug regimens, select antiemetic therapy based on the drug with the highest emetic risk
• Consider using histamine 2 blocker or proton pump inhibitors to prevent dyspepsia, which can mimic nausea
• Consider and address other potential causes of emesis in cancer patients


Neurokinin-1 (NK-1) Receptor Antagonists

<table>
<thead>
<tr>
<th></th>
<th>Dose on Day of Chemotherapy</th>
<th>Dose on Subsequent Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aprepitant</td>
<td>PO: 125 mg</td>
<td>PO: 80 mg days 2 and 3</td>
</tr>
<tr>
<td>Fosaprepitant</td>
<td>IV: 150 mg</td>
<td></td>
</tr>
<tr>
<td>Netupitant-palonosetron</td>
<td>PO: 300 mg netupitant/0.5 mg palonosetron oral in single capsule (NEPA)</td>
<td></td>
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<tr>
<td>Rolapitant</td>
<td>PO: 180 mg</td>
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</tbody>
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Serotonin Antagonists

<table>
<thead>
<tr>
<th>Dosage Forms</th>
<th>Before Chemotherapy (day 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolasetron</td>
<td>PO: 100 mg</td>
</tr>
<tr>
<td>Granisetron</td>
<td>PO, IV, Patch</td>
</tr>
<tr>
<td></td>
<td>IV: 1 mg or 0.01 mg/kg</td>
</tr>
<tr>
<td></td>
<td>PO: 2 mg</td>
</tr>
<tr>
<td></td>
<td>Patch: 3.1 mg/24 hrs</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>PO, IV</td>
</tr>
<tr>
<td></td>
<td>IV: 8 – 12 mg or 0.15 mg/kg</td>
</tr>
<tr>
<td></td>
<td>PO: 16 or 24 mg</td>
</tr>
<tr>
<td>Palonosetron</td>
<td>PO, IV</td>
</tr>
<tr>
<td></td>
<td>IV: 0.25 mg</td>
</tr>
<tr>
<td></td>
<td>PO: 0.5 mg</td>
</tr>
</tbody>
</table>


Corticosteriods

<table>
<thead>
<tr>
<th>Before Chemotherapy (day 1)</th>
<th>After Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone (Decadron®)</td>
<td>IV: 12 – 20 mg IV</td>
</tr>
<tr>
<td></td>
<td>PO: 8 mg daily 2-4</td>
</tr>
<tr>
<td>Methylprednisone (Medrol®)</td>
<td>IV: 125 – 500 mg every 6 hours</td>
</tr>
</tbody>
</table>

## Antipsychotics

<table>
<thead>
<tr>
<th>Dosage Forms</th>
<th>Dose</th>
<th>After Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olanzapine</td>
<td>PO: 10 mg</td>
<td>PO: 10 mg daily days 2-4</td>
</tr>
</tbody>
</table>


## Additional Antiemetic Options

<table>
<thead>
<tr>
<th>Dosage Forms</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prochlorperazine</td>
<td>PO, IV, IM, PR: PO/IV/IM: 10 mg every 4-6 hours, PR: 25 mg every 12 hours</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>PO, IV, PR: 10 – 25 mg every 4-6 hours, PR: 50 – 100 mg every 6-8 hours</td>
</tr>
<tr>
<td>Promethazine</td>
<td>PO, IV, PR: PO/IV/PR: 12.5 – 25 mg every 4 hours</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>PO, IV: 1 – 2 mg every 4 - 6 hours</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>PO, IV: 1-2 mg every 6 hours</td>
</tr>
<tr>
<td>Dronabinol</td>
<td>PO: 5 – 10 mg every 3 - 6 hours</td>
</tr>
<tr>
<td>Nabilone</td>
<td>PO: 1 - 2 mg every 12 hours</td>
</tr>
<tr>
<td>Metoclopramide</td>
<td>PO, IV: IV: 1-2 mg/kg 2 hours after chemotherapy, PO: 0.5 mg/kg every 6 hours days 2-4</td>
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Breakthrough Emesis

• No benefit from repeat dosing of 5-HT3 antagonists in acute phase
• Add NK-1 receptor antagonists if not previously included
• Choose medication with alternative mechanism
  • Anti-psychotic
  • Benzodiazepine
  • Cannabinoid
  • Metoclopramide
  • Phenothiazine
  • Corticosteroid


Refractory Emesis

• No benefit from repeat of agents initially used
• Change serotonin antagonist
  • If originally used ondanestron, switch to palonsetron
• Add metoclopramide, benzodiazepines, or antipsychotics

Anticipatory Emesis

- Occurs in patients with poor control in previous cycles
  - Best prevention is optimal antiemetic therapy during each cycle of chemotherapy
- Behavioral therapies with systematic desensitization
  - Relaxation, hypnosis, music therapy
- Acupuncture/acupressure
  - Psi bands™, Sea bands™
- Benzodiazepines
  - Alprazolam 0.5 – 1 mg PO TID (beginning the night before treatment)
  - Lorazepam 0.5 – 2 mg PO (night before and morning of treatment)


Oral Chemotherapy Related Adverse Events
Oral Targeted Agents Versus Traditional Chemotherapy

- Do not attack all rapidly dividing cells
- Side effect profiles can be different
- Toxicity profile differs based on drug target
- May be able to target more than one domain within the cancer cell, potentially increasing the side effect profile


Common Terminology Criteria for Adverse Events (CTCAE)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Mild, asymptomatic or with mild symptoms; clinical or diagnostic observation, no need for intervention</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Moderate, minimal, limits normal activities of daily living for that age group; noninvasive intervention indicated</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Severe, disabling, or medically significant without being life threatening; however, hospitalization is indicated</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Life-threatening, urgent intervention indicated</td>
</tr>
<tr>
<td>Grade 5</td>
<td>Death related to the adverse event</td>
</tr>
</tbody>
</table>

As side effect severity increases, more likely to consider dose reduction/dose interruption.

Oral Chemotherapy: Adverse Effects

- Alopecia
- Anemia
- Cardiotoxicity
- Constipation/diarrhea
- Delayed wound healing
- Fatigue
- Fluid retention
- Flu-like symptoms
- GI perforation
- Hand-foot syndrome
- Hearing changes
- Hepatotoxicity
- Hot flashes
- Hypertension
- Hypothyroidism
- Interstitial pneumonitis
- Metabolic abnormalities
- Mucositis/stomatitis
- Nail changes
- Nausea and vomiting
- Neuropathy
- Ocular toxicities
- Organ changes
- Osteoporosis
- Pulmonary toxicity
- Sex/sexuality
- Skin toxicities
- Thrombocytopenia
- Thrombosis

Gastrointestinal Toxicities

- Diarrhea
- Mucositis/Stomatitis
- Nausea/Vomiting
Diarrhea

• Moderate to severe
  • 14% of chemotherapy agents
• Causes
  • Direct and indirect toxic effects of treatment
  • Abdominal/pelvic radiation
  • Surgical intervention of GI tract
  • Malignancy
  • Infection

http://www.cancer.gov/about-cancer/treatment/side-effects/constipation/GI-complications-hp-pdq#link/stoc_h2_1

Diarrhea Management

• Treatment
  • Loperamide
    • 4mg PO at the first sign of diarrhea
    • 2mg PO q 2h until diarrhea free for 12 hours
    • Do not take > 12 tablets/day
  • Diphenoxylate/atropine
    • 5 mg PO QID
    • May alternate with loperamide
  • Octreotide
    • 50-150 mcg SQ q 8h; up to 500 mcg SQ q8h

• General Supportive Care
  • Hydration
  • Electrolytes
  • Diet modification-BRAT
  • Probiotics?

http://www.cancer.gov/about-cancer/treatment/side-effects/constipation/GI-complications-hp-pdq#link/stoc_h2_1
Mucositis (Stomatitis)

- Inflammation of GI mucosa
- Onset: 5-10 days
- Duration: 1-6+ weeks
- Complications
  - Pain, nutrition, infection
- Risk Factors
  - Poor oral health
  - Tobacco and alcohol
  - Females > Males
  - Dehydration
  - Chemotherapy regimen: especially high doses
  - Radiation

Mucositis (Stomatitis) Management

- Prevention
  - Good oral hygiene
  - Baking soda and salt rinses; saline rinses swish/spit QID
    - 1 tsp salt, 2 tsp baking soda, 8 oz warm water
  - MTOR inhibitors: dexamethasone mouth rinse swish/spit QID
- Treatment: supportive management
  - Oral hygiene
  - Topical/systemic analgesics
  - “Magic” mouthwash
  - Anti-infectives
    - Candida
    - HSV

http://www.oralcancerfoundation.org/complications/mucositis.php
http://www.cancernetwork.com/cancer-management/dermatologic-adverse-events-associated-systemic-anticancer-agents#sthash.T3Cy5yTU.dpuf
Dermatological Toxicities

- Hand and Foot Syndrome
- Nail Toxicity
- Photosensitivity
- Rash

Hand Foot Skin Reaction (HFSR) and Hand Foot Syndrome (Palmar-plantar erythrodysesthesia (PPE))

- Distinct in cause and presentation
- HFSR
  - 10% - 60% of patients on multi-kinase inhibitors
  - Localizes to areas of pressure or friction
- PPE
  - 30% of patients treated with capecitabine
  - Rupture of small capillaries
  - Diffuse edema and redness on palms and soles of feet

HFSR and PPE

- **Mechanism**
  - Immune response, damage blood vessels in hands and feet, or lower temperature in these areas
- **Dose and exposure related**
- **Onset:** 2-4 weeks after initiation
- **Resolves over 1-2 weeks after drug discontinuation**
- **Surfaces exposed to repetitive friction or pressure**
- Redness and swelling of palms and soles, may progress to dryness, scaling, pain, itching, blisters, and ulceration


HFSR and PPE Management

- **Prevention**
  - Remove pre-existing hyperkeratotic areas
  - Manicure/pedicure prior to and during treatment if develop
  - Shock absorbers in shoes
  - Avoid hot water and direct sunlight
  - Avoid undue pressure or rubbing of skin during initial 2-4 weeks
- **Treatment**
  - Opioids or NSAIDs
  - Topical high potency steroid creams
  - Ice packs/refrigerate creams for comfort
  - Keratolytic/urea moisturizers

Nail Toxicity

- Mee’s lines: transverse white lines
- Beau’s lines: transverse grooves or lines
- Melanonychia: melanin pigmentation of nail plate
- Paronychia: periungual inflammation
  - Epidermal growth factor receptor (EGFR) inhibitors and capecitabine
  - Management: moisturizing creams, topical/systemic antibiotics
- Subungual hemorrhages
  - 60% sorafenib, 30% sunitinib


Photosensitivity Management

- Prevention
  - Use sunscreen or protective clothing, even on cloudy days
  - Sunblock with a physical barrier (zinc oxide)
  - Avoid tanning booths
- Treatment
  - Use cool wet dressings
  - Apply lotions
  - Topical or oral steroids if severe
- UV Recall Reaction
  - May occur within 1 week of sunburn and may be more severe than primary sunburn

Shields RM. Pharmacist’s Letter 2004 (May); 20: 200509
Papulopustular Rash (acneiform)

- EGFR-"turns off the signal" for skin cells to grow normally
- Onset: 7-10 days; Peak: 2nd week
- Usually mild to moderate in severity, can progress to life threatening
  - Resolves within 1-2 weeks after drug discontinuation
- Patient counseling: rash may be surrogate marker of response

Rash Toxicity Prevention

- Mild soap, free from alcohol and perfume, in addition to moisturizing with
  emollient to area at least twice a day
- Avoid hot baths or showers, loose or soft clothing
- Preemptive skin examination
- Avoid skin exposure
  - SPF >30, with UVA and UVB protection
- Emollients
- Topical/oral antibiotics
  - Minocycline, doxycycline, clindamycin 1%
- Antihistamines
  - Hydroxyzine, diphenhydramine, loratadine

Maculopapular Rash (morbilliform eruption)

- Typically starts on trunk, may involve extremities
- Onset: ~ 2 weeks
- Management:
  - Moisturizing creams, gentle skin care, steroid cream

Cardiovascular Toxicities

- Hypertension
- QT Prolongation
- Ventricular Dysfunction
- Venous Thromboembolism

http://www.cancernetwork.com/cancer-management/dermatologic-adverse-events-associated-systemic-anticancer-agents
Hypertension

- Occurs in up to 30% of patients on vascular endothelial growth factor (VEGF) inhibitors
  - Normally, VEGF works to produce nitric oxide (NO)
  - NO is crucial in vascular homeostasis, leading to increased vascular dilation, permeability and decreased vascular resistance
- Evaluate patients prior to starting anti-VEGF therapy then periodically thereafter
  - Start antihypertensive therapy per general guidelines
- Guidelines follow that of the general population
  - Reduce sodium intake
  - Weight loss
  - Exercise
  - Medications

QT prolongation

- Primarily with multi-target kinase inhibitors
  - Thought to be due to inactivation of the PI3K/AKT/mTOR pathway or EGFR
- Black box warning for nilotinib and vandetanib
- Consider patient specific risk factors
  - Hypokalemia and hypomagnesaemia
  - Underlying cardiovascular disease
  - Concurrent QT prolonging drugs
- Consider baseline ECG and periodic monitoring

Ventricular Dysfunction

- Thought to be type II cardiotoxicity
  - Stems from decreased myocardial coordination
  - Most likely does NOT result in myocardial death
- Multifactorial cause
  - Inhibition of receptors that affect cardiac contractility
    - May be direct or bystander “target” of oral chemotherapy
- Review patient for underlying risk factors and correct if possible
  - Consider baseline LVEF monitoring and periodic follow-up per manufacturer recommendation


Venous Thromboembolism

- Risk Factors:
  - Specific cancer
  - Tumor burden
  - Anticancer treatment
    - Angiogenesis inhibitors, immunomodulatory agents
  - Surgery
  - Familial thrombophilia
  - Previous venous thromboembolism
  - Immobilization
  - Age
  - Central lines/catheters
- Management:
  - Routine primary prophylaxis not recommended
    - Exceptions: post major surgery up to 4 weeks, immunomodulatory agents
  - Treatment:
    - Aspirin
    - Low molecular weight heparin
      - Dalteparin 200 units/kg SQ once daily x 30 days, then 150 units/kg SQ once daily
      - Enoxaparin 1 mg/kg SQ BID
    - Monitoring: severe renal impairment, low body weight, thrombocytopenia
    - Warfarin and other oral anticoagulants are not recommended
    - Duration: 3-6 months to indefinite

## Miscellaneous Toxicities

<table>
<thead>
<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Alopecia</td>
</tr>
<tr>
<td>Arthralgias/Myalgias</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Hepatic</td>
</tr>
<tr>
<td>Hypothyroidism</td>
</tr>
<tr>
<td>Metabolic</td>
</tr>
<tr>
<td>Ocular</td>
</tr>
<tr>
<td>Pulmonary</td>
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</tbody>
</table>

### Alopecia

- Head, face, arms, legs, underarms, pubic area
- May fall out entirely, gradually, or in sections/patches
- Onset: 7-10 days, increase 1-2 months
- Regrow 1-3 months after, completely 6-12 months
  - Texture, color changes
- Grade 1: < 50% hair loss
- Grade 2: ≥ 50% hair loss, wig or hair piece necessary

[http://www.cancer.net/navigating-cancer-care/side-effects/hair-loss-or-alopecia]
Alopecia Management

- Expectations
- Hair and scalp care
  - Scalp sunscreen
- Wigs and hairpieces
- Mild shampoos
- Soft hairbrush
- Low heat when drying hair
- Do not use rollers to set hair
- Do not color hair or get a permanent
- Short hair cut
- Sunscreen SPF 15, sun block, hat or scarf to protect scalp

http://www.cancer.net/navigating-cancer-care/side-effects/hair-loss-or-alopecia

Arthralgias/Myalgias

- Arthralgias: symmetrical joint aches
- Myalgias: muscle pains
  - Improves with use and exercise
- Treatment
  - Exercise
  - Acupuncture
  - Yoga
  - Weight loss
  - Simple analgesics to high dose NSAIDs

Fatigue

- Multifactorial
  - Thyroid function, insomnia, depression, pain, underlying malignancy
- Impairs quality of life, relationships, mood, commitment to therapy
- Lifestyle interventions
- Complementary therapies
- Cautious use of erythropoietin stimulating agents (ESAs) in anemic patients
- CNS stimulants
  - Methylphenidate: 5 mg PO BID; max 40 mg/day
  - Corticosteroids- short term
    - Dexamethasone 4-8 mg/day

Hepatic Toxicity

- Includes asymptomatic LFT elevations, chronic hepatitis with or without necrosis, cholestasis, sinusoidal obstruction and acute liver failure
- Causes
  - Direct tumor effects
  - Direct therapy-induced hepatotoxicity
  - Prothrombotic effects
- Usually not fatal, reversible
- Types of injury
  - Ductal injury with cholestasis
  - Parenchymal cell injury with steatosis
  - Sinusoidal obstruction syndrome (SOS)/veno-occlusive disease (VOD)
  - Fibrosis or necrosis

King PD. The Oncologist 2001;6(2): 162-176.
Hepatic Toxicity

- Risk Factors
  - Preexisting liver disease
  - Chemotherapy agents
  - Concomitant hepatotoxic medications
  - Infection or reactivation of infections
  - Coexisting medical conditions
- Evaluation
  - Synthetic function: serum albumin, prothrombin time
  - Estimates of cellular injury: AST, ALT
  - Cholestasis or duct injury: ALK phos, GGT, direct bilirubin
- Management
  - Dose reductions
  - Hold therapy
  - Permanent discontinuation

King PD. The Oncologist 2001;6(2): 162-176.

Hypothyroidism

- Seen primarily with agents for renal cell carcinoma
- Includes subclinical lab abnormalities
- Multiple proposed mechanisms
  - VEGF inhibition/destructive thyroiditis
  - Increased T₃ and T₄ metabolism
  - Competitive inhibition with iodine
- Assess TSH/T₃/T₄ at baseline
  - Consider TSH at the beginning of each cycle and T₄ supplementation if symptoms present
- Patient should have routine thyroid assessment
- Thyroid replacement (if warranted)

Metabolic Abnormalities

- Includes hyperglycemia and dyslipidemias
  - Thought to be due to PI3K/AKT/mTOR inhibition
- Assess labs at baseline and periodically thereafter
  - Treat with medication as indicated
- Guidelines for treatment follow that of general population
  - Diet
  - Exercise
  - Medications

Ocular Toxicity

- Includes a wide range of ocular disorders
- Thought to be due to EGFR, PDGF, and c-Kit inhibition
- Use with caution in patients with dry eyes, contact use, or a history of ocular disorders
- Temporarily discontinue use for eye pain, swelling, redness, blurred vision or other visual impairment
  - Refer to ophthalmologist if symptoms do not resolve or for severe pain or sensory defects

Pulmonary Toxicity

- Includes pneumonitis, interstitial lung disease, pleural effusions
- Occurs from numerous agents with multiple mechanisms of action
  - Black box warning with idelalisib, methotrexate
- Multiple proposed mechanisms
  - Cell mediated autoimmune response
  - Apoptosis of type I and II pneumocytes
  - Reduction of lung structure remodeling
  - Decreased alveolar regeneration from EGFR inhibition
- No good monitoring or prevention guidelines
  - Use caution in patients with underlying lung disease or previous lung radiation


Long Term Side Effects

- Fertility
- Neuropathy
- Organ Damage
- Secondary Malignancies
- Sensorial Losses
Teratogenicity

- Factors in fetal risk
- Ethical issues
- Precautions
- Risk dependent on gestational age
- Methotrexate: greatest risk of fetal loss
- Other considerations:
  - Supportive care agents
  - Maternal toxicity
  - Altered kinetics
  - Risk of late effects


Secondary Malignancies

- Most common
  - AML (acute myeloid leukemia) and MDS (myelodysplastic syndrome)
- Secondary leukemias
  - PARP inhibitors
- Solid tumors
  - Vemurafenib and dabrafenib: squamous cell carcinoma of skin

When to Contact the Physician

- A fever of 100.4°F or greater (taken by mouth)
- Bleeding or unexplained bruising
- A rash or allergic reaction, such as swelling of the mouth or throat, sudden severe itching, trouble breathing or swallowing
- Intense chills
- Pain or soreness at the chemo injection site or catheter site
- Unusual or new kind of pain, including intense headaches
- Shortness of breath or trouble breathing
- Diarrhea that lasts 2-3 days
- Vomiting that lasts more than a day or two
- Bloody stool or blood in your urine
- Any new or unusual problem that is causing concern

Summary

- Important to discuss risk of CINV with patients starting chemotherapy treatment
- Use of an optimal prophylactic regimen is the best strategy for CINV prevention
- Many challenges exist for patients while taking oral oncologics
- Essential to counsel patients on adverse effects and their management
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