Thursday
CONGRESS NEWS

ELEVATE YOUR PASSION
ADVANCE OUR PROFESSION

congress.ons.org • #ONSCongress

Personal Wellness

What's Inside

- Schedule at a Glance
- Spotlight: Healthy Nurse, Healthy Nation™
- Nurse Self-Care and Wellness
- Healthy Living Tips and Recipes

Sponsored by Takeda

Takeda ONCOLOGY

ONS Oncology Nursing Society

ONS 42ND ANNUAL Congress

May 4–7, 2017 • Denver, CO

Thursday, May 4
Schedule At A Glance

6–7:30 am

Breakfast Symposia
See pages 58–60 of your Conference Guide for details.

6:30–7:30 am

Congress 101
Mile High Ballroom 1 A–C

7:45–9:15 am

Opening Ceremony: Stand Up, Speak Up, Listen Up: How to Empower Patients and Inspire Colleagues
Bellco Theater

9:45–11 am

American Association for Cancer Research/ONS Research Session: Genomics and Precision Medicine R
Mile High Ballroom 2/3 B–C

From GI to GI: Working With Sensitive Issues AP
Mile High Ballroom 1 A–C

Global Oncology Nursing 101
Mile High Ballroom 4 D–F

Improving Patient Outcomes: It's All About Teamwork CP
Mile High Ballroom 4 A–C

Patient Flow and Satisfaction: Navigating Through Systems L
Mile High Ballroom 1 D–F

Reaching New Heights One Benchmark at a Time AP
201–207

What's Guiding Your Actions? Translating Guidelines Into Practice L
601–607

What's Up, What's Down? Identifying Signs of Sepsis CP
Bellco Theater

11 am–4:15 pm

Learning Hall Activities
ONS Learning Hall

11:15 am–12:15 pm

Learning Hall Theater Presentations
See page 56 of your Conference Guide for details.

Advance Your Career Through Awards, Grants, and Scholarships
Career Fair Pavilion

Certification Renewal Revealed: An Insider's Guide to ILNA
ONS Booth

Industry-Supported Poster Presentation
1 CNE Contact Hour
Industry ePoster Lounge

11:15 am–1:30 pm

Team Science: A Discussion With the Experts
Mile High Ballroom 2/3 A

12:15–1:45 pm

Lunch Symposia
See pages 58–60 for details.

12:30–1:30 pm

Industry-Supported Poster Presentation
Industry ePoster Lounge

Simulation Clinic: Extravasation: Did Everything Right, and It Still Goes Wrong
ONS Booth

Certification: Opening Doors to New Opportunities
Career Fair Pavilion

Networking Roundtable Discussion on the ONS Communities
Attendee Networking Area

1:45–2:45 pm

Learning Hall Theater Presentations
See page 56 of your Conference Guide for details.

Best Practice Exchange
ONS Booth

Best Practices for Abstract Writing and Developing Your Presentation
Career Fair Pavilion

Roundtable Discussion With the Editor of the *Oncology Nursing Forum*
Attendee Networking Area

2:45–3:15 pm

Best of ONS Abstracts: At Home and Abroad, Oncology Nurses at Work L
Mile High Ballroom 1 D–F

Best of ONS Abstracts: Develop and Retain APNs AP
201–207

Best of ONS Abstracts: From Primary Care to Specialty Care L
601–607

Best of ONS Abstracts: Improving Care With Technology CP
Mile High Ballroom 4 A–C

Best of ONS Abstracts: Navigating the Fog of Fatigue and Cognitive Impairment R
Mile High Ballroom 2/3 B–C

Best of ONS Abstracts: Successful Training to Impact Care CP
Bellco Theater

Best of ONS Abstracts: Taking on Challenges in the Care of Patients With Cancer R
Mile High Ballroom 2/3 A

Best of ONS Abstracts: Using Guidelines and Precision Medicine for Quality Care AP
Mile High Ballroom 1 A–C

2:45–4 pm

Publishing Basics
107

3–4 pm

The ONS Standard for Educating Nurses Administering Chemotherapy and Biotherapy
ONS Booth

Tips for Writing Effective Resumes and CVs
Career Fair Pavilion

3:30–5:30 pm

Managing Pain in High-Risk Patients AP
Bellco Theater

Provide, Implement, Motivate: Effective Leadership in Nursing L
601–607

Shedding Light on the End of Life CP
201–207

Wisdom and Wit: Updates from the ONS Distinguished Nurse Researchers R
Mile High Ballroom 2/3 B–C

5:30–6:30 pm

Poster Session
ePoster Pavilion

6–7:30 pm

Dinner Symposia
See pages 58–60 fof your Conference Guide or details

ACCREDITED PROVIDER
AMERICAN NURSES CREDENTIALING CENTER

The Oncology Nursing Society is accredited with distinction as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. ONS is approved as a provider of continuing education by the California Board of Registered Nursing, Provider #2850.
The contact hours earned from this educational opportunity qualify for initial oncology nursing certification and renewal via ILNA.
Visit www.oncc.org for complete details on oncology nursing certification.

CP Clinical Practice

For Nurses Working in Acute Care or Ambulatory Settings

AP Advanced Practice

For Advanced Practice Nurses

L Leadership/Management/ Education

For Current or Future Nurse Leaders, Administrators, Managers, and Educators

R Research

For Doctorally Prepared Nurses Involved in Research Science, Doctoral Students, and Nurses Interested in Research

My Sessions Today

QUICK GLANCE

Thursday • May 4

9:45–11 am	**Global Oncology Nursing 101** • Mile High Ballroom 4 D–F
	Improving Patient Outcomes: It's All About Teamwork CP Mile High Ballroom 4 A–C
	What's Up, What's Down? Identifying Signs of Sepsis CP Bellco Theater
	From GI to GI: Working With Sensitive Issues AP Mile High Ballroom 1 A–C
	Reaching New Heights One Benchmark at a Time AP 201–207
	Patient Flow and Satisfaction: Navigating Through Systems L Mile High Ballroom 1 D–F
	What's Guiding Your Actions? Translating Guidelines Into Practice L 601–607
	American Association for Cancer Research/ONS Research Session: Genomics and Precision Medicine R Mile High Ballroom 2/3 B–C
2:45–3:15 pm	**Best of ONS Abstracts: Improving Care With Technology** CP Mile High Ballroom 4 A–C
	Best of ONS Abstracts: Successful Training to Impact Care CP Bellco Theater
	Best of ONS Abstracts: Using Guidelines and Precision Medicine for Quality Care AP Mile High Ballroom 1 A–C
	Best of ONS Abstracts: Develop and Retain APNs AP 201–207
	Best of ONS Abstracts: At Home and Abroad, Oncology Nurses at Work L Mile High Ballroom 1 D–F
	Best of ONS Abstracts: From Primary Care to Specialty Care L 601–607
	Best of ONS Abstracts: Navigating the Fog of Fatigue and Cognitive Impairment R Mile High Ballroom 2/3 B–C
	Best of ONS Abstracts: Taking on the Challenges in the Care of Patients With Cancer R Mile High Ballroom 2/3 A
3:30–5:30 pm	**Shedding Light on the End of Life** CP 201–207
	Managing Pain in High-Risk Patients AP Bellco Theater
	Provide, Implement, Motivate: Effective Leadership in Nursing L 601–607
	Widsom and Wit: Updates From the ONS Distinguished Nurse Researchers R Mile High Ballroom 2/3 B–C

Please visit congress.ons.org/schedule for the most up-to-date session information.

Thank You

ONS Corporate Council

ELEVATE YOUR PASSION
ADVANCE OUR PROFESSION

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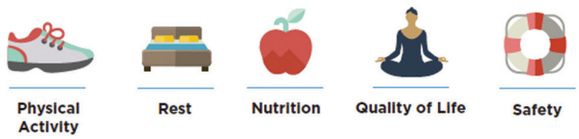
TESARO™

NOVARTIS

The Year of the **Healthy Nurse**

The Oncology Nursing Society (ONS), is a Premier Partner of the American Nurses Association's (ANA) Healthy Nurse Healthy Nation™ Grand Challenge.

The goal is to help nurses increase their personal wellness across five domains:



Nurses are the backbone of the American Healthcare system at 3.6 million strong. Yet, there is evidence that nurses are not as healthy as the general population. More than 5,000 nurses completed a pilot study through ANA in 2013-2014 and concluded the following about nurses compared to the general population:

- Poorer eating habits
- Higher BMI
- Less sleep
- Drastically higher stress levels.

Nurses need to take better care of themselves, to take better care of patients. (ANA Executive Summary – Health Risk Assessment)

This is a call to action for all oncology nurses to support the goals of the ANA's Healthy Nurse Healthy Nation™ Grand Challenge.

What is a Grand Challenge?

A Grand Challenge is a widespread goal that addresses a problem through leadership and collaboration. ONS is proud to be a premier partner in this initiative and do our part to improve the health of our nation, beginning with the 3.6 million nurses.

The health of nurses makes a meaningful difference in the health of America. Imagine the impact nurses will have on the rest of the nation through behavior modification. The Grand Challenge will lead to becoming better role models for our children, community, and patients.

Tips for ONS Members

1. Join the Grand Challenge: www.healthynursehealthynation.org/
2. Complete the Health Risk Assessment, join a discussion community on the ANA Grand Challenge platform and begin the journey by intentionally creating a goal to improve your well-being in one of the domains.
3. Look for information, support, and opportunities to engage with other oncology nurses by reading the *ONS Voice* and following us on Facebook and Twitter.

Help ONS and ANA Make *2017 The Year of the Healthy Nurse* – join the challenge today!

HEALTHY NURSE HEALTHY NATION
leading the way to better health

Wake Your Warrior

ONS Foundation Presents

Wake Your Warrior
A Group Yoga Event

Sponsored by Pfizer Oncology

Namast'ay in bed? Not today! Take this opportunity to benefit yourself and the future of oncology nursing!

This **one-hour yoga session** will offer body and mind renewal to help you learn to be more present. Use this session to benefit you in the days ahead and in future moments with your patients.

Proceeds benefit the Ann Olson Memorial Scholarship Fund. Help oncology nurses pursue a research or clinical doctoral degree.

REGISTRATION:

Cost: $35
Registration Location: Pfizer Oncology Booth (#425)

Registration includes a yoga mat and towel along with food and refreshments after the event.

A Group Yoga Event

Saturday, May 6, 2017

Starts at 6:30 am

Please arrive a few minutes early.

Colorado Convention Center in the Mile High Ballroom Foyer

All levels welcome!

Sign up early to secure a spot!

Connect
With Your Colleagues

ONS Communities

Access to the ONS communities is included in your membership and is a great way to collaborate with your peers in a virtual, online environment covering more than 20 specialized areas of interest.

Discuss real-world issues with your peers in real-time through the ONS communities online.

F **Find people with similar interests.**

A **Ask and answer questions at the time of clinical need.**

S **Solve problems using the larger oncology nursing community.**

T **Teach others.**

Whether you have a few minutes a month or can dedicate some significant time, participating in the ONS communities helps us all advance excellence in oncology nursing and quality cancer care.

Connect With

ONS Oncology Nursing Society

www.facebook.com/OncologyNursing • www.twitter.com/OncologyNursing • www.pinterest.com/OncologyNursing
www.youtube.com/OncologyNurses • www.linkedin.com/company/oncology-nursing-society

"At least quarterly I get away for a long weekend. I either take off a Friday or Monday to visit our cabin or spend time doing yard work. Being outside and tending to our home is both great physical activity and it keeps my mind occupied on something other than work. Another way I focus on my personal wellness is to completely get rid of the electronics so I don't have to keep up with everyone else—for a bit."

Lynley Fow, ARNP, AOCNP®

Straight From the **Oncology Nurse**

It's no secret that oncology nurses face a unique challenge managing their personal wellness while also caring for patients and their families. For many, oncology is more than a profession; it's a passion. We asked ONS members to share how they handle workplace stress and practice self-care.

"Oncology nurses are privileged to care for people in a vulnerable place, to walk with them through challenges, and celebrate accomplishments. This privilege comes with emotional and physical toll. My self-care comes in many forms. Some days it's as simple as sitting outside, or taking some deep breaths during a busy day. Other days, it's a bike ride to or from work to review and let go of the day. Sharing a laugh with my co-workers outside of work also lifts my spirits. As an oncology nurse, caring for ourselves first allows us to better care for our patients."

Gwen King, RN, BSN, OCN®

"Getting enough rest is my biggest challenge. I need to spend more time having some fun, too!"

Deborah Spitzer, MSN, RN, OCN®

What are your biggest challenges, as an oncology nurse, when it comes to your personal wellness? Share your thoughts, tips, and questions at communities.ons.org.

Do You Have the **Exam Jitters?**

5 Tips to Manage Stress While Preparing for Your Certification Test

Taking your Oncology Nursing Certification Corporation Certification (ONCC) test doesn't have to be stressful. Try these tips to help calm those pre-test nerves.

1. **Get organized.** Collect your study materials and look over the test reference list. Review the test content outline and use it to create a study plan.

2. **Practice, practice, practice!** Follow your study plan and use study methods that have worked well for you in the past. Take an ONCC practice test to help you become familiar with the style and format of the actual certification test.

3. **Prepare yourself for test day.** Prepare a checklist of items you need to take to the test, including acceptable forms of identification and directions to the test center. Familiarize yourself with the test center processes and rules.

4. **Relax before the test.** Get a good night's sleep. Dress comfortably for the test, and prepare for temperature fluctuations. Remember to avoid caffeine. The timer does not stop for bathroom breaks.

5. **Test with confidence.** You've got this! Pace yourself during the test and do not change an answer unless you recall new information or misread the question. Look for answer options that embody good nursing judgment and are correct in all aspects. You'll receive your results immediately after completing the test.

And most importantly...

How Stressed **Do You Feel?**

How Stress as a Nurse is Different: The Numbers

The health of our nation's nurses is suffering compared to the general population. Nurses have a higher BMI, get less sleep, and have poorer nutrition habits. But, most of all, nurses are more stressed. In fact, the average American rings in at a stress level of 26% compared to a nurse's 81%.

A nurse's workplace environment is the number one leading factor of stress. The Oncology Nursing Society has partnered with the American Nurses Association to help solve this problem, and improve the health of nurses. **The solution is the Healthy Nurse, Healthy Nation™ Grand Challenge.**

Follow along to learn more, and find out how you get involved in making a change.

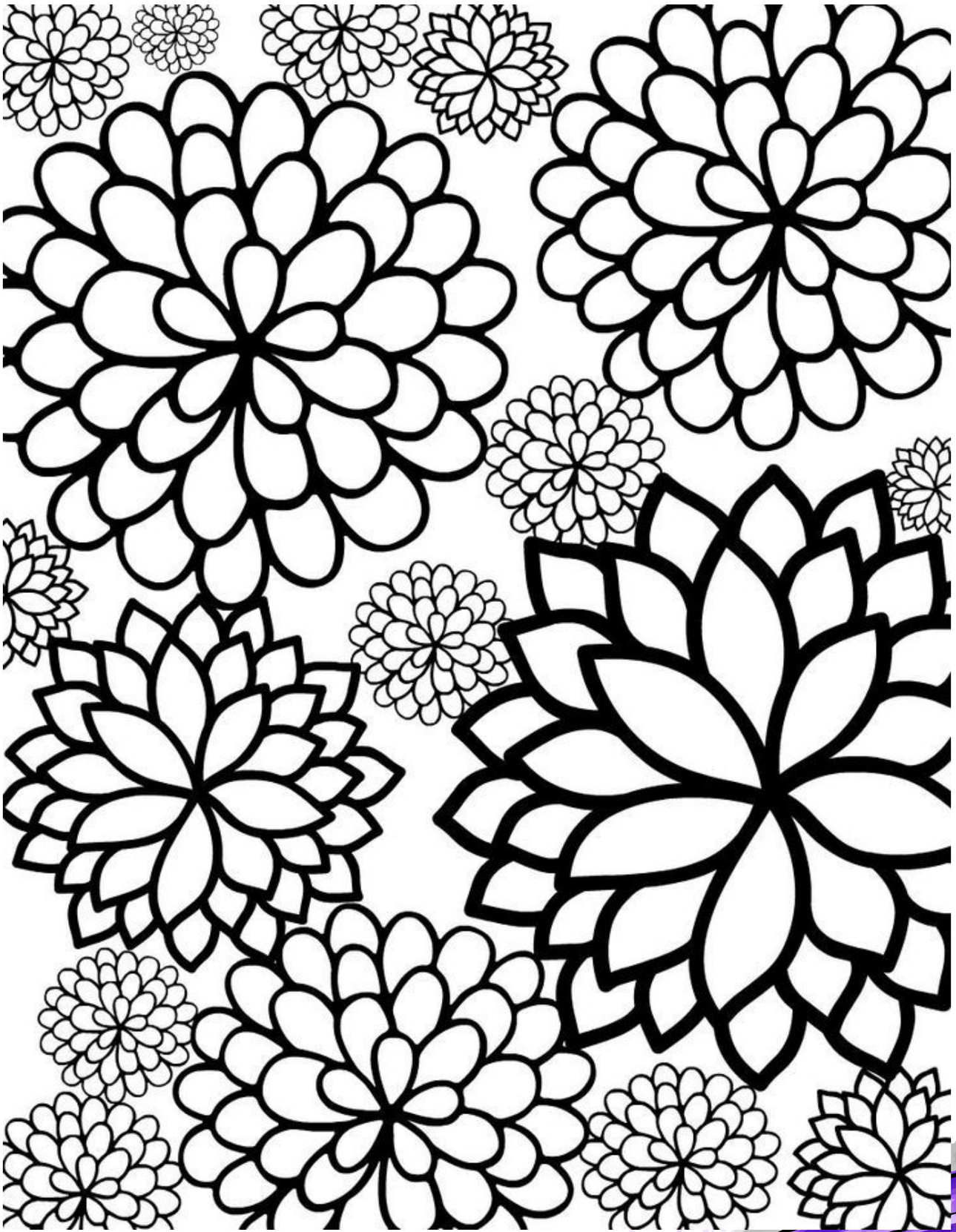
www.facebook.com/OncologyNursing
www.twitter.com/OncologyNursing
www.nursingworld.org/HealthyNurse-HealthyNation

The average nurse's stress level was reported to be

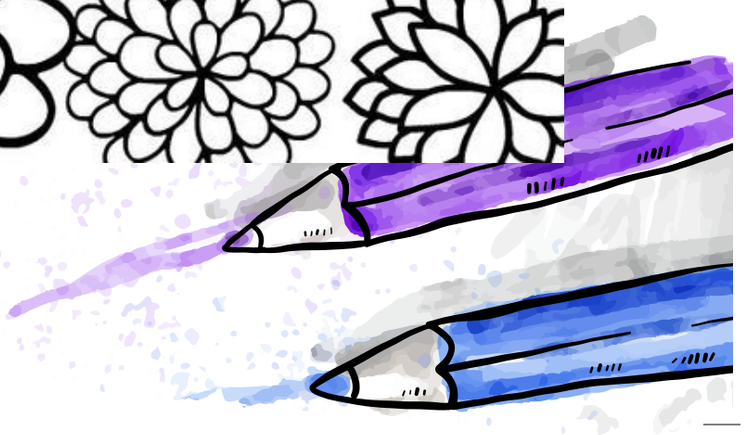
81%

American Nurses Association (2014) How do nurses measure up? A first look at results of ANA's HealthyNurse™ Health Risk Appraisal. Retrieved from https://www.americannursetoday.com/how-do-nurses-measure-up-a-first-look-at-results-of-anas-healthynurse-health-risk-appraisal


TODAY IS
GOING TO BE
AWESOME



Stop by the Attendee Networking Area in Hall C to take a break, reflect on what you've learned, and reduce stress with these coloring pages!



Encourage and Empower Cancer Survivors

New Resource Helps Lead the Way to Better Outcomes

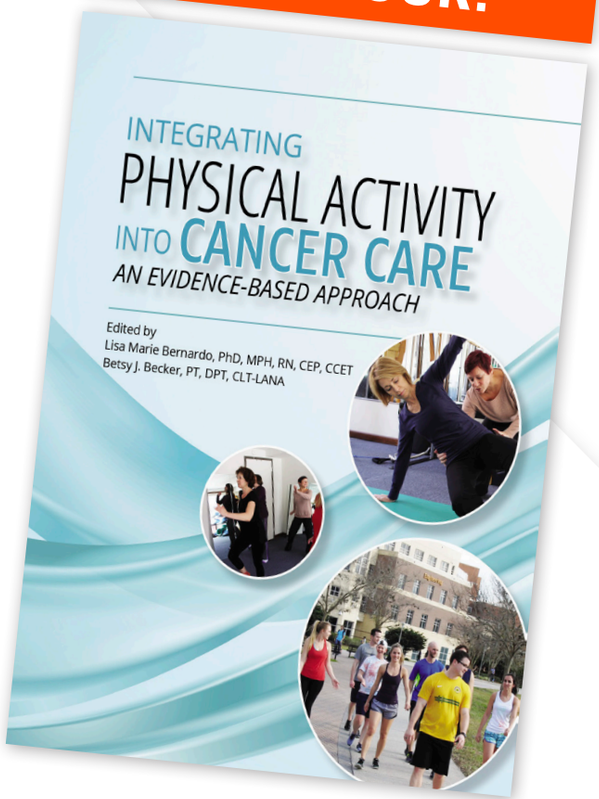
INTEGRATING PHYSICAL ACTIVITY INTO CANCER CARE: AN EVIDENCE-BASED APPROACH

Edited by L.M. Bernardo and B.J. Becker

For cancer survivors, physical activity plays an integral role in alleviating symptoms and side effects, reducing fatigue, promoting cognitive function, and improving overall outcomes and quality of life. But despite the evidence supporting the benefits of physical activity and exercise, many survivors find making this lifestyle change intimidating or overwhelming. And healthcare professionals may underestimate the positive impact that physical activity can have on patients during and following cancer treatment.

Integrating Physical Activity Into Cancer Care: An Evidence-Based Approach provides essential resources to encourage and support patients to engage in appropriate levels of exercise and physical activity throughout the cancer trajectory. Chapters highlight the benefits of physical activity in different types of cancer, strategies to assess patient motivation and readiness, ways to evaluate exercise tolerance and adherence, and resources and support groups for patients, caregivers, and healthcare professionals.

NEW BOOK!



Integrating Physical Activity Into Cancer Care: An Evidence-Based Approach
2017. 256 pages. Softcover.

ISBN: 9781935864912 • Item: INPU0626
Member Price: $45
Nonmember Price: $63

Special Offer!

Congress attendees visit the ONS store, located in the Learning Hall, and enjoy an extra 15% off your purchase. Prefer to shop online? Visit www.ons.org/store May 4 - 7 and apply code PCON17 at check out.

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Oncology Nursing Society

Wellness On-The-Go

Finding time for your own wellness can seem impossible with your busy schedule. Small changes in your daily routine help you to manage wellness while on-the-go.

Set specific goals for yourself each week. Start small and increase your goals weekly or every other week. Here are some examples, but make goals that you can achieve:

Goal 1: Exercise at least 20 minutes, three times a week.

To help ease into this goal, try thinking of exercise as general physical activity that you don't have to complete at once. Start with small increments throughout the day. For example, take a brisk walk for 10 minutes (Too cold to walk outside? Walk the halls during your break or build a little time into your stop at the grocery and cruise the isles); take the stairs instead of an elevator; or jog in place while watching TV. YouTube is a great resource for at-home workouts that are between five and fifteen minutes long.

Goal 2: Eat one piece of fruit and two vegetables each day.

Opt for meals and snacks packed with fruits, vegetables, and grains. These nutritious choices will give you the energy needed to keep up with your busy schedule.

Quick Wellness Tips

- **Add quinoa** to your soup to help you feel full.
- Store food in **serving size containers** for portion control.
- **Sprinkle cinnamon** over an apple for dessert.
- **Take a walk** on your break.

Wellness Tips for the Oncology Nurse

Your job is to care for others, and it's time to lead by example! These 10 tips will help any oncology nurse improve their own personal wellness.

1. Meal Planning

Fuel your body with the nutrients needed to produce and sustain energy. The better you feel, the better you perform and care for your patients. Rather than grab something quick between shifts, spend an hour on your day off to meal plan.

2. Unplug

Spend 30 minutes a day with all your devices turned off to let your mind slow down and adjust.

3. Bedtime Routine

Establish a regular bedtime routine for better quality sleep in preparation for the day following.

4. Stay Active

Find an activity like yoga that relaxes your body and mind. Although you're on your feet for hours at a time, it's important to dedicate time to staying active.

5. Friends & Family

It's tough to coordinate schedules or to meet up as often as you would like with your loved ones. But, it's easy and healthy to pick up the phone and talk to a friend or family member for even 20 minutes a week.

The value you bring to your patients every day is undeniable. The time you invest in yourself is essential to providing them the care they deserve.

6. Go on Vacation

Spend the weekend away relaxing with a good book, or your favorite movie. A simple change of scenery can boost personal wellness.

7. Work-Life Balance

Leave your work place stresses behind when you end a shift. Time off and at home is for you to focus on rejuvenating yourself for the following day.

8. Laugh Often

Laughter truly is the best medicine! Spend time doing what makes you happy. What makes you laugh? A movie, a friend, a certain activity?

9. Social Support

Get involved in a support group with your peers to share experiences that will bring you together. Ways to do this within ONS are through the ONS communities or your local chapter.

10. Find a Hobby

Find something to do outside of work that makes you happy. Get outside, flex your creative muscles, or volunteer.

Lead the Conversation About Weight Management

Help Patients and Survivors Make Key Lifestyle Changes

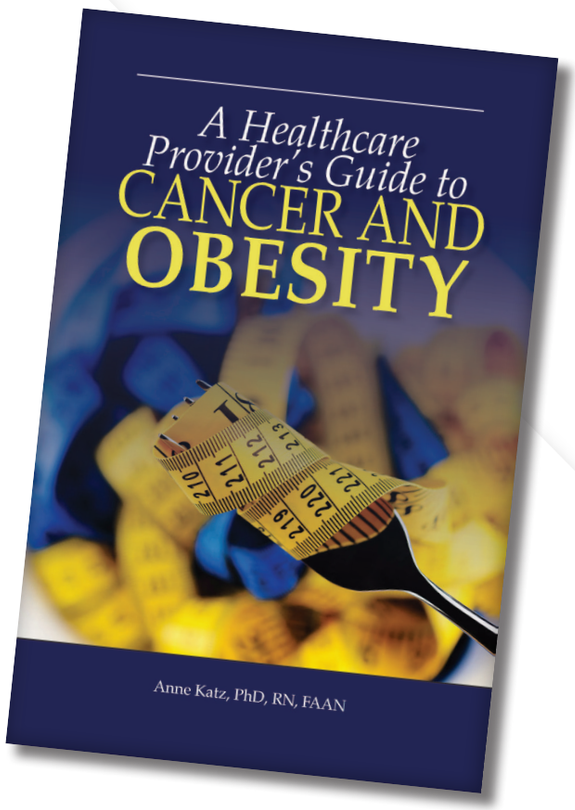
A HEALTHCARE PROVIDER'S GUIDE TO CANCER AND OBESITY

Anne Katz

Overweight and obesity play an important role in the development of various common cancers and the risk of recurrence for survivors. Patients with cancer who are overweight or obese face additional challenges, such as decreased quality of life and difficulties managing side effects. Obesity is a modifiable risk factor, and yet many survivors lack the proper education or support to successfully reduce this risk. Although healthcare providers are beginning to promote a more open dialogue with patients about weight management, barriers still exist that can delay or prevent this important conversation.

A Healthcare Provider's Guide to Cancer and Obesity provides evidence-based guidance to understanding the link between obesity and cancer and talking with patients and survivors about weight management and physical activity. Through topics such as motivational interviewing, patient challenges, mindfulness, and barriers and facilitators, each chapter addresses obstacles and issues that healthcare providers may face when discussing weight management and weight loss with patients, as well as how to overcome them.

This easy-to-use resource will equip healthcare providers with the tools needed to educate, encourage, and support survivors in making essential lifestyle changes to promote optimal health, longer survival, and better quality of life.



A Healthcare Provider's Guide to Cancer and Obesity
2017. 152 pages. Softcover.

ISBN: 9781935864943 • Item: INPU0668
Member Price: $26
Nonmember Price: $36.50

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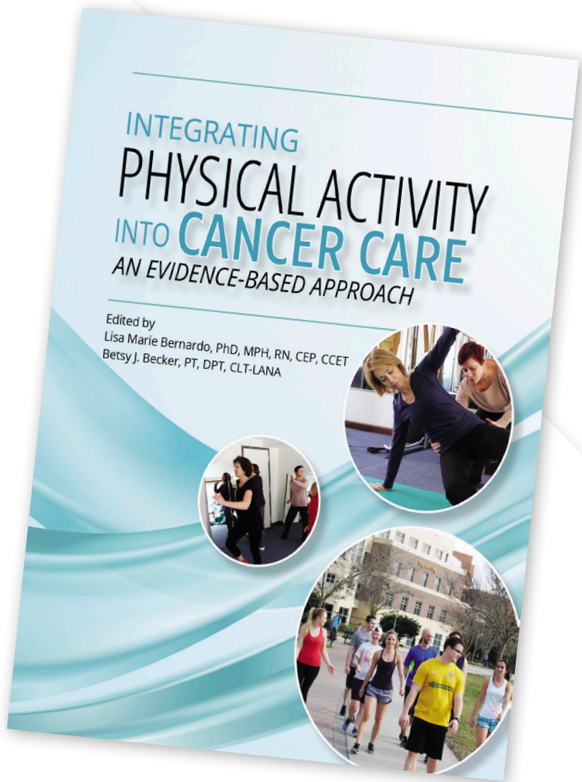

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ONS®
Oncology Nursing Society

EXTEND EFFICACY.
EXTEND THE POSSIBILITIES.

NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

IMPORTANT SAFETY INFORMATION FOR NINLARO

WARNINGS AND PRECAUTIONS

- **Thrombocytopenia** has been reported with NINLARO. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines. Adjust dosing as needed. Platelet nadirs occurred between Days 14-21 of each 28-day cycle and typically recovered to baseline by the start of the next cycle.
- **Gastrointestinal Toxicities**, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.
- **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.
- **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.
- **Cutaneous Reactions:** Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification.
- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend ixazomib in combination with

The first and only oral proteasome inhibitor

NINLARO®
(ixazomib) capsules
4mg | 3mg | 2.3mg

- The approval of the NINLARO® (ixazomib) regimen (NINLARO+lenalidomide+dexamethasone) was based on a **statistically significant ~6 month improvement in median progression-free survival vs the placebo regimen (placebo+lenalidomide+dexamethasone)**
  - Median PFS: 20.6 vs 14.7 months (95% CI, 17.0-NE and 95% CI, 12.9-17.6, respectively)
    - HR=0.74 (95% CI, 0.587-0.939); *P*=0.012

NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.

- **Embryo-fetal Toxicity:** NINLARO can cause fetal harm. Women should be advised of the potential risk to a fetus, to avoid becoming pregnant, and to use contraception during treatment and for an additional 90 days after the final dose of NINLARO. Women using hormonal contraceptives should also use a barrier method of contraception.

ADVERSE REACTIONS

The most common adverse reactions (≥ 20%) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%).

SPECIAL POPULATIONS

- **Hepatic Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.
- **Renal Impairment:** Reduce the NINLARO starting dose to 3 mg in patients with severe renal impairment or end-stage renal disease requiring dialysis. NINLARO is not dialyzable.
- **Lactation:** Advise nursing women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

DRUG INTERACTIONS: Avoid concomitant administration of NINLARO with strong CYP3A inducers.

TOURMALINE-MM1: a global, phase 3, randomized (1:1), double-blind, placebo-controlled study that evaluated the safety and efficacy of NINLARO (an oral PI) vs placebo, both in combination with lenalidomide and dexamethasone, until disease progression or unacceptable toxicity in 722 patients with relapsed and/or refractory MM who received at least 1 prior therapy.

MM=multiple myeloma; NE=not evaluable; PFS=progression-free survival; PI=proteasome inhibitor.

Please see adjacent Brief Summary.

USO/IXA/16/0100(2)

lenalidomide and dexamethasone as a category 1 treatment option for previously treated multiple myeloma.[1]

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NINLARO® (ixazomib) capsules 4mg | 3mg | 2.3mg

BRIEF SUMMARY OF PRESCRIBING INFORMATION
NINLARO (ixazomib) capsules, for oral use

1 INDICATION

NINLARO (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

5 WARNINGS AND PRECAUTIONS

5.1 Thrombocytopenia: Thrombocytopenia has been reported with NINLARO with platelet nadirs typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Three percent of patients in the NINLARO regimen and 1% of patients in the placebo regimen had a platelet count ≤ 10,000/mm^3 during treatment. Less than 1% of patients in both regimens had a platelet count ≤ 5000/mm^3 during treatment. Discontinuations due to thrombocytopenia were similar in both regimens (< 1% of patients in the NINLARO regimen and 2% of patients in the placebo regimen discontinued one or more of the three drugs).The rate of platelet transfusions was 6% in the NINLARO regimen and 5% in the placebo regimen.

Monitor platelet counts at least monthly during treatment with NINLARO. Consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

5.2 Gastrointestinal Toxicities: Diarrhea, constipation, nausea, and vomiting, have been reported with NINLARO, occasionally requiring use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea was reported in 42% of patients in the NINLARO regimen and 36% in the placebo regimen, constipation in 34% and 25%, respectively, nausea in 26% and 21%, respectively, and vomiting in 22% and 11%, respectively. Diarrhea resulted in discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.

5.3 Peripheral Neuropathy: The majority of peripheral neuropathy adverse reactions were Grade 1 (18% in the NINLARO regimen and 14% in the placebo regimen) and Grade 2 (8% in the NINLARO regimen and 5% in the placebo regimen). Grade 3 adverse reactions of peripheral neuropathy were reported at 2% in both regimens; there were no Grade 4 or serious adverse reactions.

The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimen, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Patients should be monitored for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require dose modification.

5.4 Peripheral Edema: Peripheral edema was reported in 25% and 18% of patients in the NINLARO and placebo regimens, respectively. The majority of peripheral edema adverse reactions were Grade 1 (16% in the NINLARO regimen and 13% in the placebo regimen) and Grade 2 (7% in the NINLARO regimen and 4% in the placebo regimen).

Grade 3 peripheral edema was reported in 2% and 1% of patients in the NINLARO and placebo regimens, respectively. There was no Grade 4 peripheral edema reported. There were no discontinuations reported due to peripheral edema. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

5.5 Cutaneous Reactions: Rash was reported in 19% of patients in the NINLARO regimen and 11% of patients in the placebo regimen. The majority of the rash adverse reactions were Grade 1 (10% in the NINLARO regimen and 7% in the placebo regimen) or Grade 2 (6% in the NINLARO regimen and 3% in the placebo regimen). Grade 3 rash was reported in 3% of patients in the NINLARO regimen and 1% of patients in the placebo regimen. There were no Grade 4 or serious adverse reactions of rash reported. The most common type of rash reported in both regimens included maculo-papular and macular rash. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.

5.6 Hepatotoxicity: Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly and adjust dosing for Grade 3 or 4 symptoms.

5.7 Embryo-Fetal Toxicity: NINLARO can cause fetal harm when administered to a pregnant woman based on the mechanism of action and findings in animals. There are no adequate and well-controlled studies in pregnant women using NINLARO. Ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose.

Females of reproductive potential should be advised to avoid becoming pregnant while being treated with NINLARO. If NINLARO is used during pregnancy or if the patient becomes pregnant while taking NINLARO, the patient should be apprised of the potential hazard to the fetus. Advise females of reproductive potential that they must use effective contraception during treatment with NINLARO and for 90 days following the final dose. Women using hormonal contraceptives should also use a barrier method of contraception.

6 ADVERSE REACTIONS

The following adverse reactions are described in detail in other sections of the prescribing information:

- Thrombocytopenia [*see Warnings and Precautions (5.1)*]
- Gastrointestinal Toxicities [*see Warnings and Precautions (5.2)*]
- Peripheral Neuropathy [*see Warnings and Precautions (5.3)*]
- Peripheral Edema [*see Warnings and Precautions (5.4)*]
- Cutaneous Reactions [*see Warnings and Precautions (5.5)*]
- Hepatotoxicity [*see Warnings and Precautions (5.6)*]

6.1 CLINICAL TRIALS EXPERIENCE

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety population from the randomized, double-blind, placebo-controlled clinical study included 720 patients with relapsed and/or refractory multiple myeloma, who received NINLARO in combination with lenalidomide and dexamethasone (NINLARO regimen; N=360) or placebo in combination with lenalidomide and dexamethasone (placebo regimen; N=360).

The most frequently reported adverse reactions (≥ 20%) in the NINLARO regimen and greater than the placebo regimen were diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, and back pain. Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%). For each adverse reaction, one or more of the three drugs was discontinued in ≤ 1% of patients in the NINLARO regimen.

Table 4: Non-Hematologic Adverse Reactions Occurring in ≥ 5% of Patients with a ≥ 5% Difference Between the NINLARO Regimen and the Placebo Regimen (All Grades, Grade 3 and Grade 4)

	NINLARO + Lenalidomide and Dexamethasone N=360			Placebo + Lenalidomide and Dexamethasone N=360		
System Organ Class / Preferred Term	N (%)			N (%)		
	All	Grade 3	Grade 4	All	Grade 3	Grade 4
Infections and infestations						
Upper respiratory tract infection	69 (19)	1 (< 1)	0	52 (14)	2 (< 1)	0
Nervous system disorders						
Peripheral neuropathies*	100 (28)	7 (2)	0	77 (21)	7 (2)	0
Gastrointestinal disorders						
Diarrhea	151 (42)	22 (6)	0	130 (36)	8 (2)	0
Constipation	122 (34)	1 (< 1)	0	90 (25)	1 (< 1)	0
Nausea	92 (26)	6 (2)	0	74 (21)	0	0
Vomiting	79 (22)	4 (1)	0	38 (11)	2 (< 1)	0
Skin and subcutaneous tissue disorders						
Rash*	68 (19)	9 (3)	0	38 (11)	5 (1)	0
Musculoskeletal and connective tissue disorders						
Back pain	74 (21)	2 (< 1)	0	57 (16)	9 (3)	0
General disorders and administration site conditions						
Edema peripheral	91 (25)	8 (2)	0	66 (18)	4 (1)	0

Note: Adverse reactions included as preferred terms are based on MedDRA version 16.0.

*Represents a pooling of preferred terms

(Continued on next page)

Table 5: Thrombocytopenia and Neutropenia (pooled adverse event and laboratory data)

	NINLARO + Lenalidomide and Dexamethasone N=360		Placebo + Lenalidomide and Dexamethasone N=360	
	N (%)		N (%)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Thrombocytopenia	281 (78)	93 (26)	196 (54)	39 (11)
Neutropenia	240 (67)	93 (26)	239 (66)	107 (30)

Herpes Zoster

Herpes zoster was reported in 4% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Antiviral prophylaxis was allowed at the physician's discretion. Patients treated in the NINLARO regimen who received antiviral prophylaxis had a lower incidence (< 1%) of herpes zoster infection compared to patients who did not receive prophylaxis (6%).

Eye Disorders

Eye disorders were reported with many different preferred terms but in aggregate, the frequency was 26% in patients in the NINLARO regimen and 16% of patients in the placebo regimen. The most common adverse reactions were blurred vision (6% in the NINLARO regimen and 3% in the placebo regimen), dry eye (5% in the NINLARO regimen and 1% in the placebo regimen), and conjunctivitis (6% in the NINLARO regimen and 1% in the placebo regimen). Grade 3 adverse reactions were reported in 2% of patients in the NINLARO regimen and 1% in the placebo regimen.

The following serious adverse reactions have each been reported at a frequency of < 1%: acute febrile neutrophilic dermatosis (Sweet's syndrome), Stevens-Johnson syndrome, transverse myelitis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura.

7 DRUG INTERACTIONS

7.1 Strong CYP3A Inducers: Avoid concomitant administration of NINLARO with strong CYP3A inducers (such as rifampin, phenytoin, carbamazepine, and St. John's Wort).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy:

Risk Summary: Based on its mechanism of action and data from animal reproduction studies, NINLARO can cause fetal harm when administered to a pregnant woman. There are no human data available regarding the potential effect of NINLARO on pregnancy or development of the embryo or fetus. Ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher then those observed in patients receiving the recommended dose. Advise women of the potential risk to a fetus and to avoid becoming pregnant while being treated with NINLARO. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. *Animal Data:* In an embryo-fetal development study in pregnant rabbits there were increases in fetal skeletal variations/abnormalities (caudal vertebrae, number of lumbar vertebrae, and full supernumerary ribs) at doses that were also maternally toxic (≥ 0.3 mg/kg). Exposures in the rabbit at 0.3 mg/kg were 1.9 times the clinical time averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were maternally toxic, there were decreases in fetal weights, a trend towards decreased fetal viability, and increased post-implantation losses at 0.6 mg/kg. Exposures in rats at the dose of 0.6 mg/kg was 2.5 times the clinical time averaged exposures at the recommended dose of 4 mg.

8.2 Lactation: No data are available regarding the presence of NINLARO or its metabolites in human milk, the effects of the drug on the breast fed infant, or the effects of the drug on milk production. Because the potential for serious adverse reactions from NINLARO in breastfed infants is unknown, advise nursing women not to breastfeed during treatment with NINLARO and for 90 days after the last dose.

8.3 Females and Males of Reproductive Potential: *Contraception* - Male and female patients of childbearing potential must use effective contraceptive measures during and for 90 days following treatment. Dexamethasone is known to be a weak to moderate inducer of CYP3A4 as well as other enzymes and transporters. Because NINLARO is administered with dexamethasone, the risk for reduced efficacy of contraceptives needs to be considered. Advise women using hormonal contraceptives to also use a barrier method of contraception.

8.4 Pediatric Use: Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use: Of the total number of subjects in clinical studies of NINLARO, 55% were 65 and over, while 17% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Hepatic Impairment: In patients with moderate or severe hepatic impairment, the mean AUC increased by 20% when compared to patients with normal hepatic function. Reduce the starting dose of NINLARO in patients with moderate or severe hepatic impairment.

8.7 Renal Impairment: In patients with severe renal impairment or ESRD requiring dialysis, the mean AUC increased by 39% when compared to patients with normal renal function. Reduce the starting dose of NINLARO in patients with severe renal impairment or ESRD requiring dialysis. NINLARO is not dialyzable and therefore can be administered without regard to the timing of dialysis

10 OVERDOSAGE: There is no known specific antidote for NINLARO overdose. In the event of an overdose, monitor the patient for adverse reactions and provide appropriate supportive care.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Dosing Instructions

- Instruct patients to take NINLARO exactly as prescribed.
- Advise patients to take NINLARO once a week on the same day and at approximately the same time for the first three weeks of a four week cycle.
- Advise patients to take NINLARO at least one hour before or at least two hours after food.
- Advise patients that NINLARO and dexamethasone should not be taken at the same time, because dexamethasone should be taken with food and NINLARO should not be taken with food.
- Advise patients to swallow the capsule whole with water. The capsule should not be crushed, chewed or opened.
- Advise patients that direct contact with the capsule contents should be avoided. In case of capsule breakage, avoid direct contact of capsule contents with the skin or eyes. If contact occurs with the skin, wash thoroughly with soap and water. If contact occurs with the eyes, flush thoroughly with water.
- If a patient misses a dose, advise them to take the missed dose as long as the next scheduled dose is ≥ 72 hours away. Advise patients not to take a missed dose if it is within 72 hours of their next scheduled dose.
- If a patient vomits after taking a dose, advise them not to repeat the dose but resume dosing at the time of the next scheduled dose.
- Advise patients to store capsules in original packaging, and not to remove the capsule from the packaging until just prior to taking NINLARO.

Thrombocytopenia: Advise patients that they may experience low platelet counts (thrombocytopenia). Signs of thrombocytopenia may include bleeding and easy bruising.

Gastrointestinal Toxicities: Advise patients they may experience diarrhea, constipation, nausea and vomiting and to contact their physician if these adverse reactions persist.

Peripheral Neuropathy: Advise patients to contact their physicians if they experience new or worsening symptoms of peripheral neuropathy such as tingling, numbness, pain, a burning feeling in the feet or hands, or weakness in the arms or legs.

Peripheral Edema: Advise patients to contact their physicians if they experience unusual swelling of their extremities or weight gain due to swelling.

Cutaneous Reactions: Advise patients to contact their physicians if they experience new or worsening rash

Hepatotoxicity: Advise patients to contact their physicians if they experience jaundice or right upper quadrant abdominal pain

Other Adverse Reactions: Advise patients to contact their physicians if they experience signs and symptoms of acute febrile neutrophilic dermatosis (Sweet's syndrome), Stevens-Johnson syndrome, transverse myelitis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura

Pregnancy: Advise women of the potential risk to a fetus and to avoid becoming pregnant while being treated with NINLARO and for 90 days following the final dose. Advise women using hormonal contraceptives to also use a barrier method of contraception. Advise patients to contact their physicians immediately if they or their female partner become pregnant during treatment or within 90 days of the final dose.

Concomitant Medications: Advise patients to speak with their physicians about any other medication they are currently taking and before starting any new medications.

Please see full Prescribing Information for NINLARO at NINLARO-hcp.com.

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