Patient Education and Management Strategies for TKI-related Hand-foot Skin Reaction (HFSR), Diarrhea, and Fatigue

INDICATION

STIVARGA® (regorafenib) is indicated for the treatment of patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if *RAS* wild- type, an anti-EGFR therapy.

STIVARGA is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

STIVARGA is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATOTOXICITY

- **Severe and sometimes fatal hepatotoxicity has occurred in clinical trials.**
- **Monitor hepatic function prior to and during treatment.**
- **Interrupt and then reduce or discontinue STIVARGA for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence.**

Hepatotoxicity: Severe drug-induced liver injury with fatal outcome occurred in STIVARGA-treated patients across all clinical trials. In most cases, liver dysfunction occurred within the first 2 months of therapy and was characterized by a hepatocellular pattern of injury. In mCRC, fatal hepatic failure occurred in 1.6% of patients in the STIVARGA arm and in 0.4% of patients in the placebo arm. In GIST, fatal hepatic failure occurred in 0.8% of patients in the STIVARGA arm. In HCC, there was no increase in the incidence of fatal hepatic failure as compared to placebo.

Stivarga® (regorafenib) tablets

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HFSR DEFINITION, GRADING, AND DOSE MODIFICATIONS

HFSR Definition[1]

A disorder characterized by redness, marked discomfort, swelling, and tingling in the palms of the hands and/or the soles of the feet, also known as palmar-plantar erythrodysesthesia syndrome (PPES).

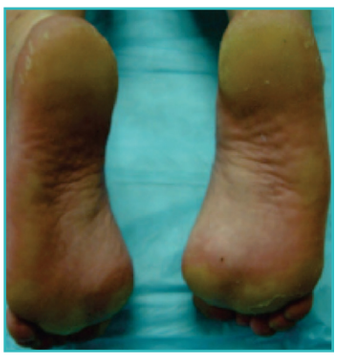
HFSR in STIVARGA® (regorafenib) Clinical Trials[2]

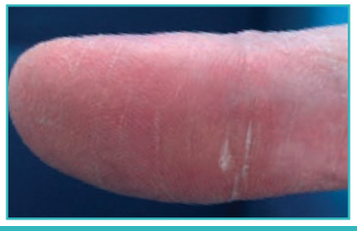
	STIVARGA Grade		Placebo Grade	
	All (%)	≥3 (%)	All (%)	≥3 (%)
CORRECT (mCRC) STIVARGA (N=500); placebo (N=253)	45	17	7	0
GRID (GIST) STIVARGA (N=132); placebo (N=66)	67	22	12	2
RESORCE (HCC) STIVARGA (N=374); placebo (N=193)	51	12	7	<1

HFSR Grading[1]

Grade 1

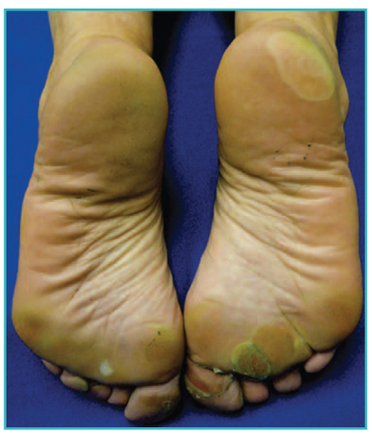
- Minimal skin changes or dermatitis (eg, erythema, edema, or hyperkeratosis) without pain





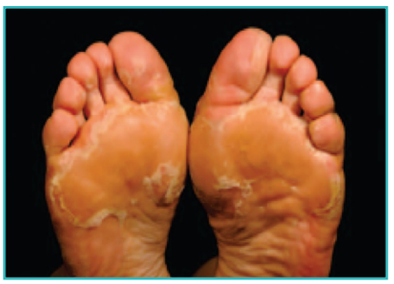
Grade 2

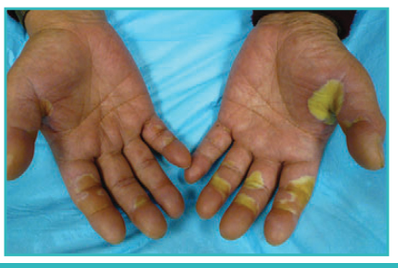
- Skin changes (eg, peeling, blisters, bleeding, fissures, edema, or hyperkeratosis) with pain; limiting instrumental ADL



Grade 3

- Severe skin changes (eg, peeling, blisters, bleeding, fissures, edema, or hyperkeratosis) with pain; limiting self-care ADL





ADL, activities of daily living.
Photos courtesy of Elizabeth Manchen, RN, MS, OCN.
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Dose Modifications for HFSR[2]

- If dose modifications are required, reduce the dose in 40-mg (one tablet) increments
- The lowest recommended daily dose is 80 mg

	Interrupt STIVARGA® (regorafenib) for the Following	Reduce STIVARGA Dose to 120 mg	Reduce STIVARGA Dose to 80 mg	Discontinue STIVARGA Permanently for the Following
HFSR	• Grade 2 HFSR that is recurrent or does not improve within 7 days despite dose reduction • Grade 3 HFSR (interrupt for a minimum of 7 days)	• First occurence of Grade 2 HFSR of any duration • After recovery of Grade 3 HFSR	• Re-occurence of Grade 2 HFSR at the 120-mg dose • After recovery of Grade 3 HFSR at 120-mg dose	• Failure to tolerate the 80-mg dose

Grading based on NCI CTCAE criteria.

Dermatological Toxicity

- In randomized, placebo-controlled trials, adverse skin reactions occurred in 71.9% of patients with STIVARGA arm and 25.5% of patients in the placebo arm including HFSR also known as PPES and severe rash, requiring dose modification
  - In the randomized, placebo-controlled trials, the overall incidence of HFSR was higher in 1142 STIVARGA-treated patients (53% vs 8%) than in the placebo-treated patients
  - Most cases of HFSR in STIVARGA-treated patients appeared during the first cycle of treatment
  - The incidences of Grade 3 HFSR (16% vs <1%), Grade 3 rash (3% vs <1%), serious adverse reactions of erythema multiforme (<0.1% vs 0%), and Stevens-Johnson syndrome (<0.1% vs 0%) were higher in STIVARGA-treated patients. Across all trials, a higher incidence of HFSR was observed in Asian patients treated with STIVARGA (all grades: 72%; Grade 3:18%)
- Toxic epidermal necrolysis occurred in 0.02% of 4518 STIVARGA-treated patients across all clinical trials of STIVARGA administered as a single agent
- Withhold STIVARGA, reduce the dose, or permanently discontinue depending on the severity and persistence of dermatologic toxicity

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HFSR MANAGEMENT CHECKLIST

HFSR Management Checklist[3-5]

HFSR Interventions	
• Consult Dose Modifications on previous page for potential dose interruptions, modifications, and/or discontinuations	❑
Patient and Caregiver Education	
• Patient should consult healthcare practitioner (HCP) at onset of any adverse event (AE)	❑
• Avoid heat, hot water	❑
• Avoid restrictive footwear; wear lace-up shoes whenever possible	❑
• Avoid vigorous and repetitive activities that place stress and/or pressure on the skin and extremities	❑
• Apply fragrance-free, alcohol-free moisturizers and emollients liberally	❑
• Wear thick gloves and socks to cover moisturizing creams	❑
• Monitor feet and hands daily for potential symptoms of HFSR	❑
Patient Assessment	
• Conduct full-body examination before treatment begins	❑
• Monitor for symptoms early and often, focusing on hands and feet, but include any areas of high friction taking into consideration the patient's occupation	❑
Control Calluses	
• Soften and remove calluses before and during treatment • Manicure or pedicure • Use of pumice stone for callus or rough spot removal • Suggest foot soaks with tepid water and Epsom salts	❑
Use of Cushion to Protect Tender Areas	
• Suggest use of insoles or cushion inserts (eg, silicon or gel) and thick socks to pad feet	❑
• Pad hard surfaces as needed to prevent the formation of calluses (eg, handles of walkers or canes)	❑
Use of Additional Creams	
• Use of creams (ie, non–urea-based creams, keratolytic creams, alpha hydroxy acids [AHAs]) as needed	❑
• HCP should determine type of cream, strength, and how often they should be used	❑
Pain Control	
• HCP may recommend/prescribe pain management medications as needed	❑
Corticosteroids	
• Topical corticosteroids may be considered for certain patients with HFSR; avoid systemic steroids	❑

NOTES

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DIARRHEA DEFINITION, GRADING, AND DOSE MODIFICATIONS

Diarrhea Definition[1]

A disorder characterized by an increase in frequency and/or consistency of bowel movements.

Diarrhea in STIVARGA® (regorafenib) Clinical Trials[2]				
	STIVARGA Grade		Placebo Grade	
	All (%)	≥3 (%)	All (%)	≥3 (%)
CORRECT (mCRC) STIVARGA (N=500); placebo (N=253)	43	8	17	2
GRID (GIST) STIVARGA (N=132); placebo (N=66)	47	8	9	0
RESORCE (HCC) STIVARGA (N=374); placebo (N=193)	41	3	15	0

Diarrhea Grading[1]

Grade 1	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
Grade 2	Increase of 4-6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL
Grade 3	Increase of ≥7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death

ADL, activities of daily living.

Dose Modifications for Diarrhea[2]

- If dose modifications are required, reduce the dose in 40-mg (one tablet) increments
- The lowest recommended daily dose is 80 mg

	Interrupt STIVARGA® (regorafenib) for the Following	Reduce STIVARGA Dose to 120 mg	Reduce STIVARGA Dose to 80 mg	Discontinue STIVARGA Permanently for the Following
Diarrhea	• Grade 3 or 4 diarrhea	• After recovery of Grade 3 or 4 diarrhea	• After recovery of Grade 3 or 4 diarrhea that followed a dose reduction	• Failure to tolerate the 80-mg dose • Grade 4 diarrhea (resume only if potential benefits outweigh the risks)

Grading based on NCI CTCAE criteria.

Most Frequently Observed Adverse Drug Reactions in mCRC (≥30%)

- The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in mCRC, respectively, were: asthenia/fatigue (64% vs 46%), pain (59% vs 48%), decreased appetite and food intake (47% vs 28%), HFSR/PPE (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%)

Most Frequently Observed Adverse Drug Reactions in GIST (≥30%)

- The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in GIST, respectively, were: HFSR/PPE (67% vs 12%), pain (60% vs 55%), hypertension (59% vs 27%), asthenia/fatigue (52% vs 39%), diarrhea (47% vs 9%), mucositis (40% vs 8%), dysphonia (39% vs 9%), infection (32% vs 5%), decreased appetite and food intake (31% vs 21%), and rash (30% vs 3%)

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DIARRHEA MANAGEMENT CHECKLIST

Diarrhea Management Checklist[4,6,7]

Diarrhea Interventions	
• Consult Dose Modifications on previous page for potential dose interruptions, modifications, and/or discontinuations	❑
• Advise intake of isotonic solution	❑
Patient and Caregiver Education	
• Patient should consult HCP at onset of any AE	❑
• Suggest keeping a diary of baseline bowel movements prior to treatment and then during treatment to help identify changes	❑
• Inform patients and caregivers about the potential changes to stool frequency and/or consistency and the need to report any changes to their healthcare team	❑
• Provide dietary advice to minimize the risk of diarrhea such as: – Low-fat, low-fiber diet – Minimize dairy, fruit, red meat, alcohol, spicy food, and caffeine	❑
• Eat small, frequent meals rather than 2 or 3 larger ones	❑
• Follow the BRAT Diet (bananas, rice, applesauce, dry toast)	❑
• Drink plenty of water	❑
Patient Assessment	
• Conduct a thorough GI history and rule out infection	❑
• Patient should consult HCP at onset of any AE	❑

GI, gastrointestinal.

NOTES

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FATIGUE DEFINITION, GRADING AND DOSE MODIFICATIONS

National Comprehensive Cancer Network (NCCN®) Cancer-related Fatigue Definition[8]

A distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning.

Fatigue in STIVARGA® (regorafenib) Clinical Trials[2]

	STIVARGA Grade		Placebo Grade	
	All (%)	≥3 (%)	All (%)	≥3 (%)
CORRECT (mCRC) STIVARGA (N=500); placebo (N=253)	64	15	46	9
GRID (GIST) STIVARGA (N=132); placebo (N=66)	52	4	39	2
RESORCE (HCC) STIVARGA (N=374); placebo (N=193)	42	10	33	5

Fatigue Grading[1]

Grade 1	Grade 2	Grade 3
• Fatigue relieved by rest	• Fatigue not relieved by rest; limiting instrumental ADL	• Fatigue not relieved by rest, limiting self-care ADL

ADL, activities of daily living.

Dose Modifications for Fatigue[2]

- If dose modifications are required, reduce the dose in 40-mg (one tablet) increments
- The lowest recommended daily dose is 80 mg

	Interrupt STIVARGA® (regorafenib) for the Following	Reduce STIVARGA Dose to 120 mg	Reduce STIVARGA Dose to 80 mg	Discontinue STIVARGA Permanently for the Following
Fatigue	• Grade 3 fatigue	• After recovery of Grade 3 fatigue	• After recovery of Grade 3 fatigue that followed a dose recduction	• Failure to tolerate the 80-mg dose

Grading based on NCI CTCAE criteria.

Most Frequently Observed Adverse Drug Reactions in HCC (≥30%)

- The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in HCC, respectively, were: pain (55% vs 44%), HFSR/PPE (51% vs 7%), asthenia/fatigue (42% vs 33%), diarrhea (41% vs 15%), hypertension (31% vs 6%), infection (31% vs 18%), decreased appetite and food intake (31% vs 15%)

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FATIGUE MANAGEMENT CHECKLIST

Fatigue Management Checklist[8]

Fatigue Interventions	
• Consult Dose Modifications on previous page for potential dose interruptions, modifications, and/or discontinuations	❑
• Physical Activity – Initiate/maintain adequate levels of physical activity such as swimming, walking, weight training	❑
• Psychosocial Interventions – Cognitive behavioral therapy/behavioral therapy – Refer to psychosocial service providers who specialize in cancer and are trained to deliver empirically based interventions	❑
• Mind-body Interventions – Mindfulness exercises, yoga, acupuncture	❑
• Pharmacologic Interventions – HCP may recommend or prescribe various pharmacologic treatments depending on severity and persistence of fatigue	❑
Patient and Caregiver Education	
• Patient should consult HCP at onset of any AE	❑
• Ensure that patients are aware of the likelihood of fatigue, the potential negative effects on ADL and quality of life, and the benefits of self-monitoring and early reporting	❑
Recommendations for Patients:	
• Do your most important tasks first	❑
• Try to stay awake during the day so you can sleep well at night	❑
• Stay as active as you can; learn about potential benefits of exercise	❑
• Take time out of the day to rest and recuperate energy levels as necessary but avoid naps	❑
• Do things you enjoy, like games, music, reading, or seeing friends	❑
• Maintain adequate fluids and nutrition	❑
Patient Assessment	
• Routinely screen for and assess fatigue at baseline before therapy	❑
• Monitor fatigue levels routinely at start of therapy and at every visit	❑
• For those reporting moderate to severe fatigue, send for a comprehensive assessment including fatigue/treatment history, physical, and laboratory evaluation, including thyroid function	❑
• Assess for any contributing factors such as pain, depression, anxiety, sleep disturbances, anemia, comorbidities, or thyroid abnormalities	❑
• Based on the grade, hold or reduce drug dose according to the guidelines provided in the package insert (PI)	❑

ADL, activities of daily living.

NOTES

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Liver Function Monitoring: Obtain liver function tests (ALT, AST, and bilirubin) before initiation of STIVARGA® (regorafenib) and monitor at least every 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Monitor liver function tests weekly in patien ts experiencing elevated liver function tests until improvement to less than 3 times the upper limit of normal (ULN) or baseline values. Temporarily hold and then reduce or permanently discontinue STIVARGA, depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis.

Infections: STIVARGA caused an increased risk of infections. The overall incidence of infection (Grades 1-5) was higher (32% vs 17%) in 1142 STIVARGA-treated patients as compared to the control arm in randomized placebo-controlled trials. The incidence of Grade 3 or greater infections in STIVARGA-treated patients was 9%. The most common infections were urinary tract infections (5.7%), nasopharyngitis (4.0%), mucocutaneous and systemic fungal infections (3.3%) and pneumonia (2.6%). Fatal outcomes caused by infection occurred more often in patients treated with STIVARGA (1.0%) as compared to patients receiving placebo (0.3%); the most common fatal infections were respiratory (0.6% vs 0.2%). Withhold STIVARGA for Grade 3 or 4 infections, or worsening infection of any grade. Resume STIVARGA at the same dose following resolution of infection.

Hemorrhage: STIVARGA caused an increased incidence of hemorrhage. The overall incidence (Grades 1-5) was 18.2% in 1142 patients treated with STIVARGA vs 9.5% with placebo in randomized, placebo-controlled trials. The incidence of Grade 3 or greater hemorrhage in patients treated with STIVARGA was 3.0%. The incidence of fatal hemorrhagic events was 0.7%, involving the central nervous system or the respiratory, gastrointestinal, or genitourinary tracts. Permanently discontinue STIVARGA in patients with severe or life-threatening hemorrhage and monitor INR levels more frequently in patients receiving warfarin.

Gastrointestinal Perforation or Fistula: Gastrointestinal perforation occurred in 0.6% of 4518 patients treated with STIVARGA across all clinical trials of STIVARGA administered as a single agent; this included eight fatal events. Gastrointestinal fistula occurred in 0.8% of patients treated with STIVARGA and in 0.2% of patients in the placebo arm across randomized, placebo-controlled trials. Permanently discontinue STIVARGA in patients who develop gastrointestinal perforation or fistula.

Dermatological Toxicity: In randomized, placebo-controlled trials, adverse skin reactions occurred in 71.9% of patients with STIVARGA arm and 25.5% of patients in the placebo arm including hand-foot skin reaction (HFSR) also known as palmar-plantar erythrodysesthesia syndrome (PPES) and severe rash, requiring dose modification. In the randomized, placebo-controlled trials, the overall incidence of HFSR was higher in 1142 STIVARGA-treated patients (53% vs 8%) than in the placebo-treated patients. Most cases of HFSR in STIVARGA-treated patients appeared during the first cycle of treatment. The incidences of Grade 3 HFSR (16% vs <1%), Grade 3 rash (3% vs <1%), serious adverse reactions of erythema multiforme (<0.1% vs 0%), and Stevens-Johnson syndrome (<0.1% vs 0%) were higher in STIVARGA-treated patients. Across all trials, a higher incidence of HFSR was observed in Asian patients treated with STIVARGA (all grades: 72%; Grade 3:18%). Toxic epidermal necrolysis occurred in 0.02% of 4518 STIVARGA-treated patients across all clinical trials of STIVARGA administered as a single agent. Withhold STIVARGA, reduce the dose, or permanently discontinue depending on the severity and persistence of dermatologic toxicity.

Hypertension: Hypertensive crisis occurred in 0.2% in STIVARGA-treated patients and in none of the patients in placebo arm across all randomized, placebo-controlled trials. STIVARGA caused an increased incidence of hypertension (30% vs 8% in mCRC, 59% vs 27% in GIST, and 31% vs 6% in HCC). The onset of hypertension occurred during the first cycle of treatment in

most patients who developed hypertension (67% in randomized, placebo controlled trials). Do not initiate STIVARGA® (regorafenib) until blood pressure is adequately controlled. Monitor blood pressure weekly for the first 6 weeks of treatment and then every cycle, or more frequently, as clinically indicated. Temporarily or permanently withhold STIVARGA for severe or uncontrolled hypertension.

Cardiac Ischemia and Infarction: STIVARGA increased the incidence of myocardial ischemia and infarction (0.9% with STIVARGA vs 0.2% with placebo) in randomized placebo-controlled trials. Withhold STIVARGA in patients who develop new or acute cardiac ischemia or infarction, and resume only after resolution of acute cardiac ischemic events if the potential benefits outweigh the risks of further cardiac ischemia.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by characteristics finding on MRI, occurred in one of 4800 STIVARGA-treated patients across all clinical trials. Perform an evaluation for RPLS in any patient presenting with seizures, severe headache, visual disturbances, confusion, or altered mental function. Discontinue STIVARGA in patients who develop RPLS.

Wound Healing Complications: Impaired wound healing complications can occur in patients who receive drugs that inhibit the VEGF signaling pathway. Therefore, STIVARGA has the potential to adversely affect wound healing. Withhold STIVARGA for at least 2 weeks prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of STIVARGA after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: STIVARGA can cause fetal harm when administered to a pregnant woman. There are no available data on STIVARGA use in pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with STIVARGA and for 2 months after the final dose.

Nursing Mothers: Because of the potential for serious adverse reactions in breastfed infants from STIVARGA, do not breastfeed during treatment with STIVARGA and for 2 weeks after the final dose.

Most Frequently Observed Adverse Drug Reactions in mCRC (≥30%): The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in mCRC, respectively, were: asthenia/fatigue (64% vs 46%), pain (59% vs 48%), decreased appetite and food intake (47% vs 28%), HFSR/PPE (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%).

Most Frequently Observed Adverse Drug Reactions in GIST (≥30%): The most frequently observed adverse drug reactions (≥30%) in STIVARGA)-treated patients vs placebo-treated patients in GIST, respectively, were: HFSR/PPE (67% vs 12%), pain (60% vs 55%), hypertension (59% vs 27%), asthenia/fatigue (52% vs 39%), diarrhea (47% vs 9%), mucositis (40% vs 8%), dysphonia (39% vs 9%), infection (32% vs 5%), decreased appetite and food intake (31% vs 21%), and rash (30% vs 3%).

Most Frequently Observed Adverse Drug Reactions in HCC (≥30%): The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in HCC, respectively, were: pain (55% vs 44%), HFSR/PPE (51% vs 7%), asthenia/fatigue (42% vs 33%), diarrhea (41% vs 15%), hypertension (31% vs 6%), infection (31% vs 18%), decreased appetite and food intake (31% vs 15%).

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References: 1. National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) v5. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50. Accessed August 22, 2018. **2.** STIVARGA [package insert] Whippany, NJ: Bayer, Inc; February 2020. **3.** McLellan B et al. *Ann Oncol.* 2015;26:2017-2026. **4.** De Wit M et al. *Support Care Cancer.* 2014;22(3):837-846. **5.** Data on File. Whippany, NJ: Bayer, Inc. **6.** Califano R et al. *Drugs.* 2015;75:1335-1348. **7.** National Cancer Institute. Managing Chemotherapy Side Effects. https://www.cancer.gov/publications/patienteducation/diarrhea.pdf. Accessed August 18, 2018. **8.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Cancer-Related Fatigue V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed February 25, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org.

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Stivarga®
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