

NDA 209935/S-019
 Page 3

NDC 0078-0909-61		Rx only 28-Day Supply	
<p>Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets)</p>		<p>This carton contains:</p> <ul style="list-style-type: none"> • Kisqali® (ribociclib) tablets: 1 individual monthly blister pack. Blister pack contains 21 tablets (200 mg per tablet). (NDC 0078-0888-21) • Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50) • Prescribing Information for Kisqali® Femara® CO-PACK. • Dosing Calendar 	
<p>200 mg daily dose (one 200 mg tablet) 21 Film-coated tablets</p>	<p>2.5 mg per tablet 28 Film-coated tablets</p>	<p>Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets)</p> <p>200 mg daily dose (one 200 mg tablet) 21 Film-coated tablets</p> <p>2.5 mg per tablet 28 Film-coated tablets</p>	
<p>Rx only</p> <p>NDC 0078-0909-61</p> <p>This carton contains:</p> <ul style="list-style-type: none"> • Kisqali® (ribociclib) tablets: 1 individual monthly blister pack. Blister pack contains 21 tablets (200 mg per tablet). (NDC 0078-0888-21) • Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50) • Prescribing Information for Kisqali® Femara® CO-PACK. • Dosing Calendar 		<p>Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets)</p> <p>200 mg daily dose (one 200 mg tablet) 21 Film-coated tablets</p> <p>2.5 mg per tablet 28 Film-coated tablets</p>	
<p>Usual Dosage: Take one 200 mg Kisqali® tablet once daily for 3 weeks followed by a one-week break, and one 2.5 mg Femara® tablet once daily for 28 days. Take with or without food. Swallow tablets whole.</p> <p>DO NOT chew, crush, or split tablets.</p> <ul style="list-style-type: none"> • Take Kisqali® Femara® CO-PACK exactly as directed by your prescriber. • Use the dosing calendar inside to keep track of your 28-day treatment. <p>Store at 20°C to 25°C (68°F to 77°F). Store in the original package. Keep this and all drugs out of the reach of children.</p> <p>For more information, visit www.KISQALI.com or call 1-844-KISQALI (1-844-547-7254)</p>		<p>Each Kisqali® tablet contains 200 mg ribociclib equivalent to 254.40 mg of the succinate salt of ribociclib.</p> <p>Each Femara® tablet contains 2.5 mg letrozole.</p>	
<p>Kisqali® (ribociclib) tablets Product of China Manufactured by Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd. 627462 Singapore</p>	<p>Femara® (letrozole) tablets Product of Switzerland Manufactured by Novartis Pharma Stein Stein, Switzerland</p>	<p>200004810-US</p> <p>Distributed by: Novartis Pharmaceuticals Corp. East Hanover, NJ 07926</p>	<p>©Novartis</p>

NDA 209935/S-019
 Page 4

NDC 0078-0916-61
Rx only
28-Day Supply

Kisqali® Femara® co-PACK
 (ribociclib tablets; letrozole tablets)

This carton contains:

- Kisqali® (ribociclib) tablets: 3 individual weekly blister packs. Each blister pack contains 14 tablets (200 mg per tablet). (NDC 0078-0895-14)
- Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50)
- Prescribing Information for Kisqali® Femara® CO-PACK.
- Dosing Calendar

400 mg daily dose
(two 200 mg tablets)
42 Film-coated tablets

2.5 mg per tablet
28 Film-coated tablets

NOVARTIS

Kisqali® Femara® co-PACK
(ribociclib tablets; letrozole tablets)

400 mg daily dose
(two 200 mg tablets)
42 Film-coated tablets

2.5 mg per tablet
28 Film-coated tablets

NOVARTIS

Rx only
NDC 0078-0916-61

Kisqali® Femara® co-PACK
 (ribociclib tablets; letrozole tablets)

This carton contains:

- Kisqali® (ribociclib) tablets: 3 individual weekly blister packs. Each blister pack contains 14 tablets (200 mg per tablet). (NDC 0078-0895-14)
- Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50)
- Prescribing Information for Kisqali® Femara® CO-PACK.
- Dosing Calendar

400 mg daily dose
(two 200 mg tablets)
42 Film-coated tablets

2.5 mg per tablet
28 Film-coated tablets

NOVARTIS

Usual Dosage: Take two 200 mg Kisqali® tablets once daily for 3 weeks followed by a one-week break, and one 2.5 mg Femara® tablet once daily for 28 days. Take with or without food. Swallow tablets whole.

DO NOT chew, crush, or split tablets.

- Take Kisqali® Femara® CO-PACK exactly as directed by your prescriber.
- Use the dosing calendar inside to keep track of your 28-day treatment.

Store at 20°C to 25°C (68°F to 77°F). Store in the original package. Keep this and all drugs out of the reach of children. For more information, visit www.KISQALI.com or call 1-844-KISQALI (1-844-547-7254)

Kisqali®
(ribociclib) tablets
Product of China
Manufactured by:
Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd.
627461 Singapore

Femara®
(letrozole) tablets
Product of Switzerland
Manufactured by:
Novartis Pharma Stein
Stein, Switzerland

0078-0916-61

Each Kisqali® tablet contains 200 mg ribociclib equivalent to 254.40 mg of the succinate salt of ribociclib.

Each Femara® tablet contains 2.5 mg letrozole.

Kisqali® Femara® co-PACK
(ribociclib tablets; letrozole tablets)

400 mg daily dose
(two 200 mg tablets)
42 Film-coated tablets

NOVARTIS

NDA 209935/S-019
 Page 5

NDC 0078-0923-61		Rx only 28-Day Supply	
Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets)		This carton contains: • Kisqali® (ribociclib) tablets: 3 individual weekly blister packs. Each blister pack contains 21 tablets (200 mg per tablet). (NDC 0078-0902-21) • Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50) • Prescribing Information for Kisqali® Femara® CO-PACK. • Dosing Calendar	
600 mg daily dose (three 200 mg tablets) 63 Film-coated tablets	2.5 mg per tablet 28 Film-coated tablets	Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets) 600 mg daily dose (three 200 mg tablets) 2.5 mg per tablet 63 Film-coated tablets 28 Film-coated tablets	
NOVARTIS			
Rx only NDC 0078-0923-61 This carton contains: • Kisqali® (ribociclib) tablets: 3 individual weekly blister packs. (NDC 0078-0902-21) • Femara® (letrozole) tablets: 1 bottle containing 28 tablets. (NDC 0078-0881-50) • Prescribing Information for Kisqali® Femara® CO-PACK. • Dosing Calendar		Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets) 600 mg daily dose (three 200 mg tablets) 2.5 mg per tablet 63 Film-coated tablets 28 Film-coated tablets	
Usual Dosage: Take three 200 mg Kisqali® tablets once daily for 3 weeks followed by a one-week break, and one 2.5 mg Femara® tablet once daily for 28 days. Take with or without food. Swallow tablets whole. DO NOT chew, crush, or split tablets. • Take Kisqali® Femara® CO-PACK exactly as directed by your prescriber. • Use the dosing calendar inside to keep track of your 28-day treatment. Store at 20°C to 25°C (68°F to 77°F). Store in the original package. Keep this and all drugs out of the reach of children. For more information, visit www.KISQALI.com or call 1-844-KISQALI (1-844-547-7254)		Each Kisqali® tablet contains 200 mg ribociclib equivalent to 254.40 mg of the succinate salt of ribociclib. Each Femara® tablet contains 2.5 mg letrozole.	
Kisqali® (ribociclib) tablets Product of China Manufactured by: Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd. 627462 Singapore	Femara® (letrozole) tablets Product of Switzerland Manufactured by: Novartis Pharma Stein Stein, Switzerland	0078-0923-61	Distributed by: Novartis Pharmaceuticals Corp. East Hanover, NJ 07924
NOVARTIS			
Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets) 600 mg daily dose (three 200 mg tablets) 2.5 mg per tablet 63 Film-coated tablets 28 Film-coated tablets		Kisqali® Femara® CO-PACK (ribociclib tablets; letrozole tablets) 600 mg daily dose (three 200 mg tablets) 2.5 mg per tablet 63 Film-coated tablets 28 Film-coated tablets	



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
Date: 5/04/2022 04:08:48PM
GUID: 502d0913000029f375128b0de8c50020