

nerlynx®
(neratinib)

PATIENT TREATMENT JOURNAL

Name: _____

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

This journal is one of the NERLYNX Patient Educational Materials.

It is provided for you to complete on a daily basis, as **soon as at the initiation of the treatment, to assist with the management of any diarrhoea you may experience.**

Please refer to the complete patient information leaflet in your medicine packaging for further information.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via the national reporting system

National Pharmacovigilance and Drug Safety Centre (NPC) / Saudi Food and Drug Authority (SFDA):

- o SFDA call center: 19999
- o E-mail: npc.drug@sfda.gov.sa
- o Website: <http://ade.sfda.gov.sa/>
- o QR Code:



and/or to the Pharmacovigilance department of Pierre Fabre laboratories RAPMS@tamergroup.com.

For extra copies, please contact RAPMS@tamergroup.com

By reporting side effects you can help provide more information on the safety of this medicine.

This guide should only be issued by a healthcare professional to adult patients starting treatment with NERLYNX.



Pierre Fabre

YOUR NEXT APPOINTMENTS

Date	Time	Things I would like to discuss with my healthcare team (such as if you have been feeling unwell, or any side effects you have been experiencing)

HOW TO USE THIS JOURNAL

Before starting treatment

- Before starting your treatment with NERLYNX, please record:
 - Your weight
 - The number of bowel movements each day, and stool consistency as shown below

Hard	Normal / Soft	Loose / Watery
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- Add up your total daily number of bowel movements and divide by the number of reported days to work out your “baseline daily bowel movements”.
- This will help you and your doctor know whether your treatment is affecting your bowel movements, and if you need to consider taking anti-diarrhoeal medicine alongside your NERLYNX treatment or adjust your daily dose.

Once you start your NERLYNX treatment

1. At the beginning of the week, make a note of the date and your weight.
2. Write your dose of NERLYNX in the second column of the table, stating the number of 40 mg tablets you have taken each day.
3. If you have been prescribed an anti-diarrhoeal medicine, make a note of the dose that you are taking each day.
4. Write down the number of bowel movements you have each day, and their consistency, hard, normal / soft or loose / watery.
5. Add up the total bowel movements each day and write that down too.

Your healthcare team is made up of your doctor, nurse and pharmacist. You should speak to your healthcare team about any side effects you have, including any side effects not listed in the package leaflet.

Example:

Before starting treatment (baseline of bowel movements)

Week commencing date: 31/10/2024 Weight: 68 kg

Note the average number of stools you had per day in the week before you start NERLYNX according to your memory, as precisely as possible.

	Number of bowel movements and stool consistency			Total number of bowel movements/day
	Hard	Normal/Soft	Loose/Watery	
Day 1 Thursday 31 /10 /2024		XX		2
Day 2 Friday 01 /11 /2024		X		1
Day 3 Saturday 02 /11 /2024				0
Day 4 Sunday 03 /11 /2024		X		1
Day 5 Monday 04 /11 /2024	X			1
Day 6 Tuesday 05 /11 /2024	X	X		2
Day 7 Wednesday 06 /11 /2024		X		1
Average daily bowel movements before treatment initiation (Add each day's total number of bowel movements and divide by number of days reported) = Baseline daily bowel movements				1.14 (=8/ 7)

Example:

Week 1

Week commencing date: 07/11/2024 Weight: 68 kg

Anti-diarrhoeal medicine: Loperamide

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1 Thursday 07 /11 /2024	240 mg	12 mg		X		1
Day 2 Friday 08 /11 /2024	240 mg	12 mg			XXX	3
Day 3 Saturday 09 /11 /2024	240 mg	12 mg			XXX	3
Day 4 Sunday 10 /11 /2024	240 mg	12 mg			XXXX	4
Day 5 Monday 11 /11 /2024	240 mg	12 mg			XXX	3
Day 6 Tuesday 12 /11 /2024	240 mg	12 mg			XXXX	4
Day 7 Wednesday 13 /11 /2024	240 mg	12 mg			XXX	3
Average number of daily bowel movements this week						3 (=21/ 7)

Before starting treatment (baseline of bowel movements)

Week commencing date: Weight:

Note the average number of stools you had per day in the week before you start NERLYNX according to your memory, as precisely as possible.

	Number of bowel movements and stool consistency			Total number of bowel movements/day
	Hard	Normal/Soft	Loose/Watery	
Day 1				
Day 2				
Day 3				
Day 4				
Day 5				
Day 6				
Day 7				
Average daily bowel movements before treatment initiation (Add each day's total number of bowel movements and divide by number of days reported) = Baseline daily bowel movements				

Week 1

Week commencing date: Weight:

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 2

Week commencing date: Weight:

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 3

Week commencing date: Weight:

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 4

Week commencing date: _____

Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 5

Week commencing date: _____

Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 6

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 7

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 8

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 9

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 10

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 11

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

Week 12

Week commencing date: _____ Weight: _____

Anti-diarrhoeal medicine :

	Daily dose of NERLYNX	Daily dose of anti-diarrhoeal medicine	Number of bowel movements and stool consistency			Total number of bowel movements/day
			Hard	Normal/Soft	Loose/Watery	
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Average number of daily bowel movements this week						

IMPORTANT CONTACT INFORMATION

Your emergency contact

Name: _____

Address: _____

Phone: _____

Mobile: _____

Email: _____

Your healthcare team

Doctor: _____

Secretary: _____

Nurse: _____

Pharmacist: _____

Address of _____

