

Mirataz[®] (mirtazapine transdermal ointment): 48-month Expiry Approved by FDA-CVM

July 20, 2020

Dear Veterinary Customers:

On October 8, 2019 the U.S. Food & Drug Administration's Center for Veterinary Medicine approved an extension of the shelf life for Mirataz[®] (mirtazapine transdermal ointment) from 30 months to 48 months. This approval was based on providing FDA-CVM with stability data that supports product integrity through 48 months post-manufacturing.

Product manufactured by Kindred Biosciences only contained the original expiration dating (30 months from date of manufacture). Dechra Veterinary Products has undertaken an over-labeling project, with FDA's knowledge, so the extended 48 month shelf life now appears on the product in the form of a tamper-evident label applied over the original expiry date on the tube and carton. The tamper-evident label will display the new expiration date as indicated in the table below. All future product manufactured in Dechra trade dress will automatically leave the manufacturing plant with the new 48 month dating, so the over-labeled product is only a temporary situation.

Lot Number	Labeled Expiration Date	New Expiration Date
NCER	Aug 2020	Feb 2022
NMAD	Apr 2021	Oct 2022
NNBB	Apr 2021	Oct 2022
NNBC	May 2021	Nov 2022

Any Mirataz cartons & tubes from lot numbers not included in the table above will not be over-labeled with the expiration extension but are valid to be used through the date that equates to 48 months post-manufacturing. The table below contains lot numbers you may already have in your inventory and their extended shelf life. Veterinary customers should apply the updated expiration date as indicated below.

Lot Number	Labeled Expiration Date	New Expiration Date
NCBF	Aug 2020	Feb 2022
NCCA	Aug 2020	Feb 2022
NECM	Nov 2020	May 2022

Lot Number	Labeled Expiration Date	New Expiration Date
NECN	Nov 2020	May 2022
NECP	Nov 2020	May 2022
NFDB	Nov 2020	May 2022
NFDC	Dec 2020	June 2022
NGES	Jan 2021	July 2022
NKAZ	Feb 2021	Aug 2022
NKBA	Feb 2021	Aug 2022
NKBB	Feb 2021	Aug 2022
NMAB	Mar 2021	Sep 2022
NMAC	Mar 2021	Sep 2022
NNCW	Apr 2021	Oct 2022
NNFC	May 2021	Nov 2022

If you have any questions about the information contained in this letter or the safe and effective use of Mirataz, please contact our Veterinary Technical Services team at 1-866-933-2472. For complete product information, please visit www.dechra-us.com.

Sincerely,



Janet Cunningham
Director, Regulatory Affairs North America