

Important Field Safety Notice

Product exchange due to an incorrectly declared expiry date

Field Safety Corrective Action for **Etermis 3**, Merz Pharmaceuticals GmbH
dated 08-June-2020

Attention: Customer

Identification of concerned products:

Batch number: **927095**

Description of the problem including the determined cause:

Dear Customer,

we detected that the above mentioned Etermis 3 batch 927095 was declared with an incorrect expiry date of 38 instead of 36 months, i.e. 2022-08 instead of 2022-06.

The expiry date is declared on the folding box, the patient label, the syringe label as well as on the label of the shipping carton (see picture below).



Merz Pharmaceuticals GmbH

Eckenheimer Landstraße 100
60318 Frankfurt am Main

Geschäftsführung: Stefan Brinkmann, Philip Burchard, Beat Neukom
Handelsregister: Amtsgericht Frankfurt am Main, HRB 53808
Rechtsform: Gesellschaft mit beschränkter Haftung
Ust-ID: DE813402170

Deutsche Bank AG
Frankfurt am Main
BLZ 500 700 10, Konto 0 340 002 500
IBAN DE67 5007 0010 0340 0025 00
BIC DEUTDEFFXXX



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It was determined that the error was caused by an incorrect date of manufacture of the semi-finished goods documented in the enterprise resource planning system, which is used by Merz Pharmaceuticals to manage business operations and customer relations. This date is used as the basis for calculating the expiry date of the finished goods. Accordingly, the expiry date is not correct.

Unfortunately, packages with an incorrectly declared expiry date have been already delivered to you as our customer.

The use of the batches with incorrect labelling of the expiry date does not present any safety concern until June 2022 when the correct expiry date is reached.

Nevertheless, as the product is not correctly labeled according to regulatory requirements we would like to draw your attention to this letter on an upcoming product exchange for the above-mentioned Etermis 3 batch.

Please note that this issue does not relate to the product itself – only the labelling. The product can be safely used as per the current Instructions for Use.

Advise on action to be taken by the customer/user:

We kindly ask you to note this update. We will contact you and supply you with new correctly declared products and ensure the exchange of all concerned remaining products you may have in stock with new deliveries until end of September 2020.

Thank you for reading this information. Please make sure that this information is forwarded within your organization and all relevant persons are aware of this Important Field Safety Notice. If packages of batch 927095 have already been sent to third parties, please forward a copy of this information or inform the below mentioned contact person.

Please keep this information at least until the action has been completed. Your national Competent Authority has received a copy of this "Important Field Safety Notice".



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Contact reference person:

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Global Medical Device Safety Officer, Global Product Safety- Merz Aesthetics

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