



Important Field Safety Notice

Etermis 3/Etermis 4 Product recall

Field Safety Corrective Action for **Etermis 3 / Etermis 4**, Merz Pharmaceuticals GmbH
dated 16-Oct-2020

Attention: Merz Customer

Identification of concerned products: Etermis3 / Etermis 4

Batch numbers:

**813030;919309;811768;813024;816785;810491;929286;918513;030188;808434;
808432;812407;817117;817119;919320;817225V;920860;921380;923669;92526
8;923225;927092;030518;811770;813020;813028;807483;812408;814979;81533
6;814874;815639;815640;923224;813031;808439;813023;919310;808433;81049
0;807484;807482;808442;927090;808435;920101;923758;929287;808443;81176
7;811771;812405;812404;813032;815337;814978;816993;817118;921079;03018
7;813038;816992;813022;813029;817225;925267;921379;925266;927091;92928
4;815641;030186;808441;811769;813027;813021;814980;814981;813025;81699
1;816787;816788;815335;920100;815642;920861;921080;817120;923226;92366
8;918514;924479;926777;927093;929285;930185;920968;812403;816786;92375
6;923757;811772;814977;808438;918512V;920969;812258;812406;818511V;92
3039;923405;926064;926065;929290;930190;923406;924014;927095;929288;92
9289;930189;930191;930517;816816;816816N;929291;926063;810968;921044;
816818;816817;926062;812744;922533;**

Description of the problem including the determined cause:

Dear Customer,

Merz is constantly improving the quality of their products to meet and exceed the expectations of our customers with respect to quality and safety. To that end, Merz is recalling the following batches of Etermis 3 / Etermis 4 as mentioned above. For our Etermis 3/ Etermis 4 products, we recently implemented additional quality controls determined the presence of particles consisting of cellulose, protein and three different plastic materials in some Etermis syringes.

Analysis of the particles determined a low theoretical probability of serious harm to our patients.

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

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However, any foreign body may induce a response possibly leading to local inflammation, either at the injection site or in adjacent tissues. To date, Merz has not received reports concerning these lots suggesting serious effects due to the potential presence of these particles.

Merz reviewed all reported adverse events and we have seen nothing unusual or any deviation from the known safety profile of Etermis 3 and 4.

However, as patient safety is paramount to Merz we will voluntarily recalling all potentially affected batches as a precautionary safety measure.

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

We kindly ask you to note this important safety information. Please send all affected Etermis 3 / Etermis 4 products of the concerned batches you may have in stock back to Merz. We will issue you with a credit note for all resent product to compensate you.

Please ensure that this information is forwarded within your organization and all relevant persons are aware of this Important Field Safety Notice. If packages of the concerned batches of Etermis 3 / Etermis 4 mentioned above have already been sent to third parties, please forward a copy of this information or inform the contact person mentioned below.

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

Contact reference person:

Alain Werbrouck

Responsible Person

Tel: +32 476 90 13 45

E-mail: alain.werbrouck@telenet.be