PREVENTIVE ACTION

Lexotan lot is suspended by Anvisa

Stability test results failed the batch. The action is preventive since the risk of problems for the users is small.

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Posted: 07/19/2017 00:08
Last Modified: 07/19/2017 14:29

Anvisa has suspended lot RJ0874 of the drug Lexotan on Wednesday (7/19). All batch stock RJ0874 (Validity 01/2019) of the drug Lexotan (bromazepam), 3 mg tablets, should be collected from the market by the manufacturer Roche Chemicals and Pharmaceuticals.

According to the company's statement, the Lexotan batch in question presented results below the specification provided for in the dissolution test in stability studies. Such studies analyze whether the pharmaceutical properties of a given drug remain stable over the shelf-life.

The other batches of the product are released. In addition, there are different generic and similar drugs on the market with the active principle bromazepan.

What is the risk?

Anvisa classified the problem as low risk, which is class 3 as provided for in Resolution RDC 55/2005. Even so, the prohibited batch should not be used.

Class 3 risk classification indicates a situation in which there is a low probability that the use or exposure to a drug may have adverse health consequences, ie the risk to the patient is low.

Check out the suspension of the Lexotan lot published in the Official Gazette (DOU) this Wednesday (7/19). (http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=50&data=19/07/2017)

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