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# Roche requests suspension of batch of melanoma drug

Company Roche Chemicals and Pharmaceuticals reported failure to produce Cotellic unit. Sale and use of the identified batch are suspended.

**By: Ascom / Anvisa****Posted: 05/05/2017 10:41****Last Modified: 05/11/2017 17:19**

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Anvisa suspended trade in lot B1009M8 of the medicinal product Cotellic (hemifumarate of cobimetinib), manufactured by the company Productos Roche Químicos e Farmacêuticos SA

In addition to the suspension of trade in the lot (<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=94&data=11/05/2017>), the Sanitary Agency also decided to suspend the use of the lot for the treatment of melanoma positive for BRAF V600 mutations that were either unresectable or metastatic.

According to a statement sent by the company Roche, a unit of tablet presented technical failure during production. A 20mg coated tablet was identified as being approximately 40% overweight relative to its original specification.

For this reason, lot B1009M8, validity 02/2018, of the drug Cotellic is suspended and the company, Products Roche Chemicals and Pharmaceuticals SA, responsible for promoting the collection of the stock of the product in question.

**Glucose suspended**

The presentation of an unsatisfactory result in the medication Glucose 5% parenteral solution caused the suspension of one of the batches of the product. The trade in lot 91379 of the drug manufactured by Halex Istar Pharmaceutical Industry as well as its use has been suspended.

According to the fiscal analysis report issued by the LACEN-BA Laboratory, lot 91379 (validity 04/24/2017) had an unsatisfactory result for the sample description test because it presented foreign material.

Resolution RE 1234/17 requires (<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=94&data=11/05/2017>) Halex to collect stock from the batch of the product concerned.


Leia as medidas sanitárias na íntegra aqui. (<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=94&data=11/05/2017>)

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