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INTERRUPTION OF MANUFACTURING

Buscopan withdrawn from the market has substitutes

Manufacturer has identified issues during accelerated stability test.

By: Ascom / Anvisa

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Surveillance and Monitoring

The Boehringer Ingelheim laboratory, maker of the drug Buscopan, is temporarily withdrawing the drug from the market. The decision is valid for the Buscopan Composite oral solution (drops) of 10mL and 20mL. The measure was adopted after the laboratory identified problems in the accelerated stability test.

The decision is preventive and serves to ensure that the product poses no risk related to the safety and quality of the medicine.

Understand the case

Why was the product withdrawn from the market?

(<http://portal.anvisa.gov.br/fiscalizacao>) The manufacturer itself identified problems during a test called "Accelerated Stability". This test serves to define the validity of the product, ie it measures how long the product remains good for consumption after its manufacture.

National Health Surveillance System
(<http://portal.anvisa.gov.br/vigilancia-sanitaria-no-brasil>)

Are there any substitute medications at the same price range?

Yes. The Buscopan Compound has the following formula: Scopolamine Butylbromide + Dipyron Monohydrate. There are at least three similar and three generic ones with the same formula in commercialization in the country. These medicines have similar prices, but it is always very important that the consumer makes a comparison of prices in pharmacies.

Education and Research
(<http://portal.anvisa.gov.br/educacao-e-pesquisa>)

Be sure to consult your pharmacist to ensure that the substitute is identical to the original medication.

Can the consumption of products that are commercially available pose a health risk?

The action is preventive and until this moment the lots of Buscopan that are in the market are released for use.

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Pesticides
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Since the company previously notified the discontinuation, was it responsible for supplying the market for at least 6 months?

This is an unscheduled type of interruption. That is, a reason of force majeure that led the factory to stop the production of the problems mentioned above.

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What is expected to return to manufacturing?

There is no forecast so far.

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