

PANAMA ORDERS THE INCLUSION OF SECURITY INFORMATION ON DRUGS

Panama's Health Ministry, through the National Directorate of Pharmacies and Drugs, Ministry of Health, adopted preventive measures regarding information to be enclosed in the drug monograph that contains the following components:

1. Resolution N° 196 of April 27, 2015 [Official Gazette N° 27781 of May 15, 2015] obliges to include within the product warnings and adverse reactions to medicines containing the component known as **immunoglobulin**, which could produce Myocardial Infarction, Cardiovascular Disease, among others.
2. Resolution N° 191 of April 22 2015 [Official Gazette N° 27783 of May 19 2015] orders that medicines containing **mycophenolate mofetil or sodium**, must present instructions to follow when the drug is combined with other immunosuppressants, as well as the possibility of respiratory or immune system disorders arising as a result of these components' intake.
3. Resolution N° 200 of April 30, 2015 [Official Gazette N° 27783 of May 19 2015] for the case of products containing **ambroxol or bromhexine**, are required to be included within the drug monograph, specifying that the product can contribute to developing serious cutaneous reactions.

It is important to note that the aforementioned Resolutions apply for laboratories, manufacturers and/or sellers which have registered products, products in process of sanitary registry or its renewal, as well as new registry requests made before the National Direction of Drugs and Pharmacies. Feel free to contact us should you need any further information on this matter.

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