



Recall – Co-Aprovel (Irbesartan) 300 mg-25 mg

October 2020

AXA PCACP, always committed to the safety and prevention of adverse events related to medically necessary medications in the treatment of our distinguished members, and in compliance with Panamanian legislation and the federal regulations that govern this Benefit Plan, responsibly notifies that, we have received information that the National Directorate of Pharmacy and Drugs (DNFD) of the Ministry of Health of Panama (MINSA) has issued an instruction to the Sanofi Laboratory for the withdrawal of the drug from the market:

Co-Aprovel (Irbesartan) 300 mg-25 mg x 14 comprimidos recubiertos.

Specific batch 9A333 (only).

Manufacturer: Sanofi-Winthrop Laboratories (France). Distributor: Sanofi-Aventis de Panamá, S.A.

This notification of withdrawal occurs once the DNFD has determined that the information provided by the manufacturer and distributor laboratory does not comply with the technical legal requirements established in the current sanitary regulations and approved by said Directorate of Pharmacy and Drugs in the Registration Sanitary Protocol, since said information or conditions under which it is being commercialized are not those accredited in the current Sanitary Registry file.

We responsibly make it known that the drug designated for recall only corresponds to the designated lot (9A333), which may have been for sale at Farmacias Arrocha and within the reach of our respected members. The rest of the batches of the same drug do not have any sales restriction and can be used safely.

We invite our members and providers to review the batch number of the **Co-Aprovel 300 mg-25 mg x 14 tablets drugs**, so that they can approach the closest Farmacias Arrocha, with the objective that they can make the change of the drug at no cost for an equivalent drug corresponding to Irbesartan 300 mg-25 mg.

We take advantage of this communication to let you know that, in view of this situation, and until a new batch of drugs is authorized by the National Directorate of Pharmacy and Drugs, once it is available in the country Since it is an imported product, the available presentation of Irbesartan 300 mg-25 mg will be the one manufactured and distributed by MK Laboratory, which can be used as an equivalent, until new batches can be dispatched



again. **Co-Aprovel of 300 mg-25 mg x 14 tablets**, once the Ministry of Health of Panama approves them.

We appreciate your kind attention and cooperation. We will be pending to clarify any questions and additional comments by phone 366-1400 and email.