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P326: Pharmacovigilance study in côte-d'ivoire on artemisinin derivatives

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Objectives

Analyze the various package leaflets on Artemisinin-based combination therapy (ACT) marketed in Côte-d'Ivoire.

Methods

Comparative study, conducted from June 1 to December 20, 2011 which included all package inserts for all ACT registered and marketed in Côte-d'Ivoire. The inserts' content was compared to that of European product descriptions; our investigation focused particularly on side effects.

Results

Regarding artemether-lumefantrine, all leaflets described digestive disorders. As far as endocrinal and metabolic systems are concerned, appetite loss and anorexia were described in 28,5% and 42,8% of leaflets. As far as skin and annexes are concerned, we found: rash (100%), pruritus (90%), slate-gray pigmentation (28%) and redness of the face (14%). Finally, only notices of plasmocid® and coartem® reported biological side effects. As regards the artesunate-amodiaquine, blood effects were described: agranulocytosis (60%), blood dyscrasia and leucopenia (40%), hemolytic anemia (20%). At the gastrointestinal level, were found nauseas, vomiting and diarrhea (80%), hepatitis (60%), fatal hepatitis (20%). On the level of the nervous system was mentioned peripheral neuropathy (80%), the extra-pyramidal syndrome (20%). At the general level, it was asthenia only found in the leaflet of camoquin plus®.

Conclusion

Information of the laboratories differing from one specialty to another for the same molecule, it would be recommended that these ones harmonize the contents of the leaflets.

Disclosure of interest

None declared.

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