

DOCUMENT TITLE: REGULATORY DIRECTIVE ON THE DISCONTINUED REGISTRATION OF ANALGIN OR NOVALGIN (GENERIC - METAMIZOLE) FORMULATIONS		
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NATIONAL AGENCY FOR FOOD & DRUG ADMINISTRATION AND CONTROL (NAFDAC)
Regulatory Directive on the Discontinued Registration of Analgin (Metamizole) or Novalgin (dipyrone)
Formulations

1.0. Purpose:

This regulatory directive aims to discontinue the registration of Analgin (Metamizole) or Novalgin (dipyrone) formulations as analgesic/antipyretic due to the risks associated with product safety. Metamizole/dipyrone is a strong analgesic and antipyretic with spasmolytic properties used as a powerful pain and fever reducer. Metamizole/dipyrone is banned in several countries because it was found to cause agranulocytosis which is a life-threatening blood disorder.

2.0. Scope:

This Regulatory Directive applies to locally-manufactured and imported Analgin (Metamizole) or Novalgin (dipyrone) formulations (all strengths and dosage forms).

3.0. Directive Details:

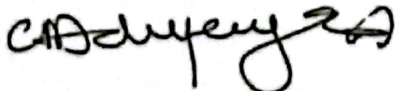
NAFDAC no longer accepts New, Renewal and Variations applications for locally-manufactured and imported Analgin (Metamizole) or Novalgin (dipyrone) formulations (all strengths and dosage forms).

Analgin (Metamizole) or Novalgin (dipyrone) have been found to cause blood-related toxicity (blood dyscrasias) including agranulocytosis and aplastic anaemia which are potentially fatal conditions.

Approved By:

Director-General (NAFDAC)

Prof. (Mrs.) Mojisola Christianah Adeyeye

Signature:  Date: 1/7/2024

Legend:

RDXX

RD: Regulatory Directive

XX: First two letters of the first two words of the document title.