

A study of fixed dose combination preparations of nutritional supplements with specific reference to iron containing preparations: assessment of rationality

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OBJECTIVES

Given the large number of nutritional supplements available in the Indian market and being one of the most prescribed drugs this study was conducted to analyse and assess these drugs and rationality of the same.

METHODS

Analysis of drug formulations enlisted under the category of nutritional supplements, under the subheading of vitamins, iron, zinc and tonics in the Drug Today was carried out for their dosage form, banned combinations, evidence of efficacy, cost, individual constituents and their amount per unit.

RESULTS

There were 2620 preparations categorized under nutritional supplements of which 2081 were found under vitamins, minerals and tonics with FDCs constituting 84.07%, 92.94% and 100% share respectively. The number of constituents in single preparation were found to

be high with highest being 30. Banned combinations were found in 33%, 14% and 69% under each of the above category. Under the category of vitamins only 34% and 12% of formulations were found to be adhering to therapeutic and prophylactic range of vitamins respectively and only 30% of those also containing minerals fell within their RDA. Among iron preparations 97% were found to be FDC with maximum no of constituent being 20 of which only 23% preparations had minerals falling within RDA. 59% of all the preparations scored 5 or less on the rationality scale.

CONCLUSIONS

Majority of the drugs were FDCs consisting of irrational drug combinations either in the form of banned drug combinations or preparations with unproven. Most of the vitamin preparations are not suitable for prophylactic use. There are a large number of "me too" preparations. There is large heterogeneity in the amount of minerals in the formulations, mostly not abiding with their RDA. The costs of formulations are relatively high.