

drug reaction in the package insert of the drug Fluconazole as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Fluconazole formulations under your jurisdiction to mention Hyperpigmentation as an adverse drug reaction in the label/Package insert/Promotional Literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,



**Dr. S. Eswara Reddy**  
**Drugs Controller General (India)**

1. Copy for information & follow-up: -  
All Zonal / Sub Zonal Offices of CDSCO.
  
2. Copy for information to: -  
JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.