

**F. No. 12-01/18-DC (Pt-337)**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
FDA Bhawan, Kotla Road, New Delhi  
(New Drugs Division)

FDA Bhawan, Kotla Road,  
New Delhi.

Dated: **09 MAR 2021**

To,

All State/UT Drugs Controllers,

**Sub: Incorporation of Tinidazole associated Skin Hyperpigmentation in the  
prescribing Information Leaflet - Reg.**

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Sir/Madam,

Tinidazole are approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including **Tinidazole** which were discussed by them in the 16th Signal Review Panel (SRP) under the programme meeting held on 27.12.2019 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the Tinidazole -ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to incorporate Tinidazole associated **Skin Hyperpigmentation** as an adverse drug reaction in to the prescribing information leaflet (PIL) of the drug Tinidazole formulations marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 20.01.2021 at CDSCO HQR, New Delhi. After detailed deliberation, the Committee has recommended that

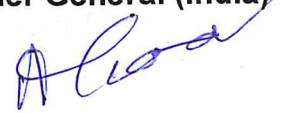
**Skin Hyperpigmentation** should be incorporated in the package insert of the drug Tinidazole as suggested by PvPI.

The recommendation of the SEC has been considered by this office.

Accordingly, you are requested to direct the manufacturers of Tinidazole formulations under your jurisdiction to mention **Skin hyperpigmentation** as an adverse drug reaction in the Package insert/Promotional Literature of the drug.

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

Yours faithfully,

  
**Dr. V.G Somani**  
**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.