F.No.12-01/18-DC(Pt-238)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road
New Delhi
Dated: 19.12.2018

To
All State/UT Drugs Controllers

Subject: - Safety guidelines for Isotretinoin - Regarding

Sir/Madam,

Isotretinoin is an oral drug used for the treatment and prevention of severe acne.

Isotretinoin capsule 10mg/ 20mg was approved by CDSCO on 21.06.2002 for treatment of cystic and conglobate acne, severe nodular acne unresponsive to antibiotic therapy with various conditions including a box warning for female patients as the drug may cause severe birth defects and patients should sign a consent form as per specified format before undertaking the treatment of Isotretinoin. Copy of the approval/permission is enclosed for ready reference.

In light of concerns raised with regard to safety of Isotretinoin, the matter has been examined by CDSCO in consultation with the Subject Expert Committee (SEC) (Dermatology & Allergy) in its meeting held on 26.07.2018.

The SEC deliberated the matter in detail and opined that the drug has favorable risk/benefit profile for the indications approved in the country. However, the following conditions should be followed during manufacture, sale and distribution of the drug as already stipulated by CDSCO at the time of approval of the drug.

1. The drug should be sold by retail on the prescription of Dermatologists only.
2. Pack of the drug should carry following Box warning-

   > This medicine may cause severe birth defects; you must not take this medicine if you are pregnant or may likely become pregnant during treatment.
   >
   > You should also avoid pregnancy for 6 months after stopping the treatment.

3. The patients should also sign a Consent Form before undertaking the treatment of Isotretinoin as already stipulated in the new drug permission.

The committee also recommended that the manufacturers should provide package insert along with their product which should be in major vernacular languages. The retail chemists should maintain the details of retail sale of the drug which should be strictly on the prescription of Dermatologist only.

Accordingly, you are requested to direct the manufacturers/retail chemists under your jurisdiction to comply with the following:-

(i) For Manufacturers:

1. Label should contain the warning 'The drug should be sold by retail on the prescription of Dermatologists only.'

2. Pack of the drug should carry following Box warning-

This medicine may cause severe birth defects; You must not take this medicine if you are pregnant or may likely become pregnant during treatment. You should also avoid pregnancy for 6 months after stopping the treatment.

3. The patients should also sign a consent form before undertaking the treatment of Isotretinoin as per the format enclosed.

4. Manufacturer should provide package insert along with their product which should be in major vernacular languages.

(ii) For retailers:

The drug should be sold by retail only on prescription of Dermatologist and the details of the sale should be strictly maintained as per requirements of D&C Rules, 1945.

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

Yours faithfully

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

Copy for information and necessary follow up to:

All Zonal/Sub Zonal offices of CDSCO.

CDSCO website.