

RECLASSIFICATION OF HYDROQUINONE 1-2% FROM COSMETICS TO DRUGS

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The Bureau of Food and Drugs (BFAD) has approved the reclassification of Hydroquinone 1 -2% Solution from Cosmetics to Drugs.

Recent study shows that the abuse of Hydroquinone 1-2% causes serious adverse reactions like convulsion and tremors. Hypersensitivity reaction have also been occasionally reported. The same study shows that prolonged use may produce hyperpigmentation known as ochronosis, which is Irreversible and users may fall Into "skin lightener trap".

Based on the foregoing, the following rules are hereby adopted:

1. The use and indication of Hydroquinone shall be restricted to pathological hyperpigmentation such as chloasma, melasma, freckles and lentigines.
2. Its use for skin bleaching and its incorporation in cosmetics for skin whitening will no longer be approved.
3. The following appropriate warnings shall be included on the labels.

3.1

Hydroquinone should not be used longer than two (2) months.

3.2

Do not apply to broken skins.

3.3

It should not be used on children under twelve (12) years of age.

3.4

Do not use to treat more than 10% of the total body surface.

Manufacturers are hereby given six (6) months from approval hereof within which to exhaust existing supplies, reformulate or apply for initial registration of Hydroquinone as Drugs.

This Memo Circular shall take effect immediately.

Adopted: 15 Aug. 1994

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