

1. promotional materials directed to physicians & health-care professionals must include:-

- The active ingredient(s) name(s).
- The trade name.
- Content of active ingredient per dosage form or regimen.
- Name of other ingredients known to cause problems.
- Approved therapeutic uses.
- Dosage form and regimen.
- Side effects and major adverse reaction. **(incidence > 1%)**
- Precautions, contraindications and warnings.
- Major interactions.
- Name and address of manufacturer or distributor.
- References to scientific literature as appropriate.
- CAPA approval number & invalidation date of promotional material.