

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Aushadh Vaban
Mohakhali, Dhaka-1212, Bangladesh

Informations Regarding Packaging Material of Medicinal Products

1. In the primary packaging of the medicine like bottle (glass/plastic), vial (glass), strip, blister and sachet following informations must be included:

- **Brand name of medicine:** Generic name should be written just beneath the Brand Name. Font Size of Brand name should not be less than 16 & for **Generic Name**, font Size should at least be 8-10. But in case of screen print & vial , special permission is required if there is not enough space.
- Generic Name with strength, monograph of active ingredient/ INN name.
- Batch Number,
- Manufacturing Date,
- Date of expiry,
- Registration number of medicine/ Marketing Authorization No (MA No/ Drug Approved Registration No (DAR No)
- Manufacturing License Number must be vividly written.
- Manufacturing Organization's Name and Full address with monogram.
- In case of contraceptive pill, specific dates of using must be clearly mentioned.

2. In case of Ampoule:

- Brand Name of medicine,
- Generic Name with strength,
- Batch Number, Mfg. Date & Exp. Date should be clearly mentioned in the body of the ampoule.



3. Secondary packaging of medicine:

- **Brand Name of Medicine:** Generic Name should be written just beneath the Brand Name. Font Size of Brand name should not be less than 16 & for Generic Name it should be at least 8-10.
- Generic Name with strength, monograph of active pharmaceutical ingredient/ INN name.
- Pack Size
- Batch Number
- Manufacturing Date
- Date of expiry
- Registration number of medicine/ Marketing Authorization Number (MA Number)
- Manufacturing License Number.
- Manufacturing Organization's Name and Full address with monogram.
- In case of the packaging of Combipack, active ingredients of each type should be clearly mentioned.
- Mention the Maximum Retail Price/ Indicative Price fixed by the Directorate General of Drug Administration.
- Security Marking & Hologram Printing must be done to prevent counterfeit medicine.
- In case of adverse reaction of medicine, box warning or special cautions which is directed & authorized by Drug Administration must be mentioned in red color.
- Storage temperature must be printed on the basis of Stability study data.
- In case of every medicine except the OTC, "**Prescription Only**" should be printed in red color in the visible space of packaging.
- **In case of Imported Medicine**, Manufacturing Company's Name & its agents name & address, DAR Number, Expiry Date & Maximum Retail Price should be printed in Bangla. Sticker will not be acceptable at any cost in case of expiry date & maximum retail



price. Security Marking & Hologram Printing must be added to prevent counterfeit medicine.

- In case of **toll manufacturing of medicines**, “Manufactured by X for Y” should be mentioned clearly in the packaging materials.
- In case of **Powder For Suspension (RFS)**, preparatory procedure & “shake the bottle before use” must be mentioned. The sentence, “After preparation, deadline of use/consumption (up to 7/14 days)” must be printed.
- In case of **physician sample** this sentence (“**Physician Sample, Not for Sale**”) should be printed in **red color**.
- Mention the **indications** only approved by **Drug Control Committee**.
- In case of antibiotics like medicines, “fulfill the course of antibiotics according to the advice of the physician” must be printed.
- “Keep out of reach of children” should be printed.

4. Special Warning/Caution:

- Sentences like “Suitable For Injection” “For parenteral Injection (IM Injection/ IV Injection/ Both Injection) (Only Muscle/ Only Vein/ Both) must be printed. For IM/IV Injection “It is to be used under medical Supervision” must be printed.
- As a part of warning, in case of the packaging of IV fluid (The solution should not be used if it is found to be turbid or sedimented) must be printed.
- In case of eye drops, nasal drops & ear drops the word “**STERILE**” must be clearly printed.
- In case of the packaging of Veterinary Medicine, this sentence “Only for the use of animals” should be printed in red letter and where applicable “Withdrawal Time” must be mentioned. The word “Vet” must be printed with the Brand Name.
- In case of Liniment, lotion, cream, ointment, liquid antiseptic the sentence “**For External Use Only**” must be printed.

A handwritten mark consisting of a circle with a stylized 'M' inside, followed by a long diagonal line extending to the right.

- In case of every type of vaccine, insulin, serum, antitoxin, blood products storage temperature, total amount of dose in container, cautions must be mentioned.
- In case of suppository, this sentence **“Not for Oral Use”** must be printed.
- In the packaging of medicines like Narcotic, Psychotropic, Anesthetic (General & Local), Antineoplastic, Antibacterial- these sentences **“To be dispensed & sold only by the prescription of a registered physician”** & **“Should not be used more than the mentioned amount in the prescription”** must be printed.
- Special caution (e.g: Should not be used during pregnancy, Drowsiness may occur in case of sedatives)should be mentioned.



18 DEC 2018

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