

DRUG LABELS

Drug labeling is all the printed information that is provided with a drug. This labeling is regulated by the Food and Drug Administration (FDA), which specifies exactly what must appear on the label.

Manufacturer Labels

The manufacturers place their information on the medication bottle or package they provide to the health-care facilities and pharmacies. The manufacturers also include information on the package insert they include with the medication. The label contains the strength of the medication, the form it comes in, the quantity of medication in the container, the lot and NDC numbers, the manufacturer name, storage information, and expiration dates. Prescription medications will have “RX ONLY” on the label. A controlled dangerous substance (CDS) will have the schedule number on the label and a large C with the Roman numeral inside, e.g., ©. The package insert provides more detailed information for the health-care provider in regard to this medication, including, but not limited to, forms and strengths of the drug available, mixing of and stability of the medication, adverse reactions, patient counseling information, and full prescribing information.

Medication Labels

The medication label placed on the container by the dispensing pharmacist contains important information (Fig. 5-2). It includes the pharmacy’s name, address, and telephone number, which are useful in case the patient needs to contact the pharmacy with problems or questions. The dispensing date is also on the label. This date may differ from the date when the prescriber wrote the prescription. The pharmacist originates an Rx number that identifies this unique prescription in the computer system and on the label. The patient can refill the prescription by using this number. The patient’s full name and address is included, as are the name of the medication. In addition, the following must be included on the label:

- **Strength of drug dispensed:** It is important to know the concentration of the medication, meaning how weak or strong it is.
- **The dosage form:** It is the ordered medication being dispensed in the form of a tablet, liquid, or aerosol, for example.
- **Amount of drug dispensed.** The amount of medication contained in the prescription bottle must be listed. This information is listed as a number and, if the medication is in liquid form,

<p>(A) Rx Pharmacy</p>	<p>Rx Pharmacy 345 Cherry Lane Hometown, VA 22958</p>	<p>(B) Date filled: 11/14/20xx</p>
<p>(C) Rx 001234789</p>		
<p>(D) Martin, Connie 789 Beach Tree Drive Hometown, VA 22958</p>		
<p>(E) Take 1 tablet by mouth at bedtime Colace tabs Qty: 30</p>	<p>(G) 3 refills Discard after 11/14/20xx</p>	
<p>(F) Mfg: Purdue</p>		
<p>(H) Carl Newell M.D. 125 Main Street Hometown, VA 22958</p>		

FIGURE 5-2: Sample medication label. A drug label has several parts: (A) name, address, and telephone number of the pharmacy; (B) date when the prescription was filled; (C) Rx (prescription) number; (D) name and address of the patient; (E) directions to the patient (Latin abbreviations translated into English for the patient), and name and quantity of medication; (F) the manufacturer; (G) number of refills and expiration date; and (H) name of the prescriber.