

# GENERIC DRUGS

## Generic vs. Brand



*Did you know that over 80% of the prescriptions filled in the United States are filled with generic medications?*

### Generic Drugs

As common brand name medications continue to lose patent protection, the number of generic medications will continue to increase. Although generic medications are used to fill most of the prescriptions in the United States, there are still misconceptions surrounding them.

#### What is a generic medication?

Medications can have up to 3 names; a chemical name (scientific name), a generic name, and a trade (or brand) name. Both the generic and trade name are recognized by the pharmaceutical industry. When a medication is initially approved by the FDA, it is

given a set number of years, usually 20, from when the drug application is initially submitted. After this time period elapses, other manufacturers can submit an application to the FDA to bring generic versions of the drug to market. These generic versions contain the identical active ingredient as the brand name medication in the same strength and dosage form.

#### Are generic drugs safe and effective?

The FDA requires generic medications to meet the same requirements for strength, purity, and quality as brand name medications. Generic companies must also

comply with the same strict current Good Manufacturing Practices (cGMP) rules that regulate the entire production process. Generic medications must be shown to be “bioequivalent” to the brand name product. Bioequivalence means that the generic product is absorbed in the body at the same rate and to the same extent as the brand name medication. In order to produce the same therapeutic effect. Batches of generic medications are subject to the same testing and requirements that are applied to batches of brand name drugs.

## Generic Drugs Continued

Since the brand name medication has already undergone the studies to show the medication is safe, generic companies are not required to complete this testing. The bioequivalence testing is what is most important to show that the generic drug will produce the same effects in the body as the reference brand name drug.

### How can generic medications differ from brand name drugs?

While generic drugs are required to contain the same active ingredient and produce the same therapeutic effects in the body, they can differ from the brand name in some ways. These often include things such as:

- Shape
- Color
- Packaging
- Inactive ingredients (fillers, dyes)

The above differences in no way affect how the drug works in the body, but rather are due to manufacturing procedures and/or trademark reasons. Any inactive ingredients that are used in either brand or generic products must be considered safe by the FDA.

### Who makes generic medications?

Years ago there were many generic manufacturers. As time went on, manufacturers have merged or in some cases have been purchased by brand name manufacturers. At this time, generic

medications are produced by both generic and brand name manufacturers. In some instances, when a patent expires for a brand name medication, the first generic that is approved is given 6-months of exclusivity in the prescription drug market. That means other generic manufacturers must wait that time period before they can begin to distribute their approved generic medications. This is one of the reasons that prices for new generic medications not fall until several months after they are launched. In other cases once the patent for a brand name medication expires, many approved generics may be available. This usually leads to lower cost generics at the time of launch rather than having to wait for increase competition.

## Recent Medications That Have Gone Generic

The following charts will show you the most recent medications that have gone generic as well as a list of medications to go generic with *potential dates*:

| Drug Name            | Generic Name              |
|----------------------|---------------------------|
| Lovaza               | omega-3 acide etyl esters |
| Renvela              | sevelamer carbonate       |
| Actonel (150mg only) | risedronate               |
| Micardis             | telmisartan               |
| Celebrex             | celecoxib                 |
| Intuniv              | guanfacine                |
| Exforge              | amlodipine/valsartan      |
| Exforge-HCT          | amlodipine/valsartan/HCTZ |

Below is the list of medications with a *potential date* as to when they will go generic

| Drug Name    | Generic Name          | Date      |
|--------------|-----------------------|-----------|
| Mirapex ER   | pramipexole ER        | 2/1/2015  |
| *Nexium      | esomeprazole          | 2/20/2015 |
| Welchol      | colesevelam           | 3/2/2015  |
| Abilify      | aripiprazole          | 4/30/2015 |
| Voltaren gel | diclofenac gel        | 5/31/2015 |
| EpiPen       | epinephrine           | 6/22/2015 |
| Namenda      | memantine             | 7/11/2015 |
| Aggrenox     | asa/dipyridamole      | 7/31/2015 |
| AndroGel     | testosterone gel      | 8/31/2015 |
| Daytrana     | methylphenidate patch | 9/1/2015  |

*\*Although a generic has been approved, there is currently only one manufacturer and therefore there may be supply issues at this time*