Identifying tablets & capsules by imprint codes

Every prescription and over-the-counter (OTC) oral solid dosage form (ie, tablets and capsules) must have a unique imprint code according to federal law. These imprint codes are sometimes referred to as a “marking” or “inscription” and are usually a combination of letters and numbers, although they can be a company logo or the name of the drug. Usually imprints are cryptic codes that mean something only if you know where to go to break the code.

Interestingly, although federal law mandates that all prescription dosage forms have the unique imprint, there is no official list to look up the codes. Therefore, healthcare professionals must use commercial references to determine what a product is based on the imprint.

Drug identification is important in overdoses. If a patient presents with a half-consumed bottle of tablets or capsules, the identity of the potential toxin must be known in order to appropriately treat the patient.

Being able to identify drugs based on imprint codes is also important when patients bring their medications into the hospital, when patients bring all their medications into your office all mixed in one container, or when a patients thinks a prescription has been misfilled. For these reasons, it is important to know which references can be used to identify tablets and capsules based on imprint codes.

We are fortunate to have several references available from any computer terminal at Shands at UF that will identify imprint codes. IDENTIDEX®, which is marketed by Micromedex, is available through the Health Center Library’s databases page at http://healthcare.micromedex.com/. Under the “Find Drugs and Substances” section of this page, select Toxicology, then select IDENTIDEX®.

You can simply put the imprint code in the search field, which will lead you to a list of products.

Clinical Pharmacology (http://cpip.gsm.com/) can also be used to identify products. Select the “Drug Products” tab at the top of the page, then the “Product Identification” link. Follow the directions for use in the middle frame, which are a little more difficult than IDENTIDEX®. Our own research suggests that IDENTIDEX® is easier to use than Clinical Pharmacology.

Another reference that is free and can be used from any computer with Internet access is RxList (www.rxlist.com). Select the “RXLIST ADVANCED SEARCH” link, the scroll down to the “RxList-ID Imprint Code Identification” search field.

Our own research has found that IDENTIDEX® is the best reference used to look up imprint codes. IDENTIDEX® identified the most tablets and capsules based on imprint codes. However, RxList is pretty good—considering that it is available anyone free of charge. Our research also found that drugs on the market for less than a year, generic drugs, and OTC drugs are the most difficult to identify using imprint codes. Even using the best references, there will be drugs that cannot be identified.

REFERENCES
Few studies have compared the fibrates to each other. Further definitive trials are needed before firm comparisons of effectiveness between these medications can be made. Thus far, studies have shown gemfibrozil to be similarly effective as fenofibrate in reducing triglycerides. However, there is some data that suggests that patients who cannot tolerate or who do not respond to gemfibrozil will benefit from fenofibrate.

Most patients should respond satisfactorily to gemfibrozil; however, fenofibrate may offer an alternative in some patients who do not respond to gemfibrozil.

Micronized fenofibrate tablets and capsules are not bioequivalent. The bioavailability of micronized fenofibrate in the tablet formulation is significantly greater than the bioavailability for the capsule formulation. The 200-mg capsule is considered comparable to the 160-mg tablet; and the 67-mg capsule is considered equivalent to the 54-mg tablet (ie, the tablets are approximately 25% more bioavailable).

Fenofibrate tablets were added in the Formulary while fenofibrate capsules were designated nonformulary and not available. When an order for fenofibrate capsules is received, a P&T authorized interchange will be done for the capsule formulation. The 200-mg capsule = 54 mg-tablet. Fenofibrate tablets were approved based on a lack of data to support its addition in the Formulary.

Tegaserod is used in the treatment of irritable bowel syndrome. It was originally considered by the P&T Committee in September 2002 and listed based on a lack of data to support its addition in the Formulary. Since 12 months have passed, tegaserod was reconsidered for formulary addition. Tegaserod has been the number 1 nonformulary drug in terms of doses dispensed.

Tegaserod has a labeled indication for the short-term treatment of constipation-predominant irritable bowel syndrome (IBS) in women. Tegaserod is the only drug in the US with a labeled indication for constipation-predominant IBS. Research suggests neurotransmitters are involved in the pathogenesis of IBS. Tegaserod stimulates serotonin Type-4 receptors, which are thought to trigger the release of other neurotransmitters that stimulate intestinal peristalsis and secretion.

The labeled dosage of tegaserod is 6 mg twice a day before meals for 4 to 6 weeks. Responders may receive an additional 4 to 6 weeks. The safety and efficacy of tegaserod in children has not been established; however, research in adolescents is being planned.

The quality of the published evidence for the treatment of IBS is not good. Defining and measuring the appropriate response variables for IBS is difficult. However, several studies have now been published that support the use of tegaserod for the short-term treatment of IBS in women. Available studies suggest tegaserod may not be as beneficial in men; however, these studies are underpowered to detect sex-based differences in efficacy. Also, there still is no long-term efficacy data for IBS.

There is some concern about the use of tegaserod. The limited available published data suggest the treatment effect in IBS is small and may decrease with time. Since IBS is a chronic condition, this could be a problem. Considering the level of evidence, modest benefit, and cost, tegaserod should be reserved for patients with constipation-predominant IBS who have no response to fiber or laxatives and antispasmodics.

There are limited data available to support the off-labeled use of tegaserod. Only 1 small study is published supporting the use of tegaserod for GERD. There are no published data for other potential off-labeled uses (eg, chronic constipation, gastroparesis). Abstracts on these topics have been presented at GI meetings and publication is expected.

Tegaserod was added in the Formulary; however, the volume of use will be monitored. If usage is higher than expected, an audit of its use will be considered. Tegaserod will not be listed in the Charitable Care Formulary.

Arsenic trioxide is used for the treatment of leukemia. The labeled indication for arsenic trioxide is for the induction of remission and consolidation of acute promyelocytic leukemia (APL) in patients who are refractory to or have relapsed from retinoid and anthracycline chemotherapy and whose APL is characterized by the presence of the t(15;17) translocation of the PML/RAR-alpha gene expression. APL is a subset of acute myelocytic leukemia with this specific chromosomal abnormality. Current treatment for newly diagnosed APL includes all-trans retinoic acid (ATRA) in combination with anthracyclines for consolidation, then ATRA for maintenance therapy. Although most patients respond to standard therapy, about one-third of patients who achieve remission will relapse. Patients with APL who relapse are treated with stem cell transplantation (SCT), when an HLA-compatible donor is available.

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Misunderstandings about COX-2 inhibitors

“COX-2 inhibitors” are the newest nonsteroidal anti-inflammatory drugs (NSAIDs) on the market (ie, celecoxib [Celebrex®], rofecoxib [Vioxx®], and valdecoxib [Bextra®]). These agents are specific for the second isozyme of cyclooxygenase (COX). The COX enzymes catalyze the conversion of arachidonic acid to prostaglandins and thromboxanes, which subsequently regulate physiologic processes throughout the body. When prostaglandins cause inflammation and pain, interruption of the production of prostaglandins results in a favorable therapeutic effect. When beneficial prostaglandins are inhibited (ie, those responsible for protection of the gastrointestinal tract or perfusion of the kidney), adverse effects result.

COX-2 inhibitors were developed because traditional NSAIDs are non-specific cyclooxygenase inhibitors that inhibit pain and inflammation associated with the COX-2 enzyme as well as normal regulatory effects associated with the COX-1 enzymes. The inhibition of COX-1 in the gastrointestinal tract prevents the protective effects of this enzyme. COX-2 inhibitors have less GI toxicity because these drugs have little effect on the COX-1 enzyme.

Although COX-2 inhibitors have less GI toxicity, they do cause GI toxicity. Because of a selection bias (ie, using COX-2 inhibitors selectively in patients who are risk for NSAID-induced toxicity), GI toxicity with COX-2 inhibitors may be misperceived as being common. There are other misperceptions associated with the COX-2 inhibitors.

Because these are newer agents, some clinicians incorrectly think COX-2 inhibitors are more effective than traditional NSAIDs. COX-2 inhibitors are no more effective than traditional NSAIDs.

There are no published data that show that COX-2 inhibitors are better anti-inflammatory agents or better pain relievers. This is particularly relevant for intermittent and short-term use. The better GI toxicity profile of COX-2 inhibitors is most relevant for long-term use. Since COX-2 inhibitors are no more effective, traditional NSAIDs are the preferred agents for short-term and intermittent use.

When COX-2 inhibitors were developed, it was hoped they would be less nephrotoxic. Unfortunately, COX-2 plays an important role in maintaining renal perfusion in the kidney. Kidney tissue is rich with the COX-2 enzyme. COX-2 inhibitors are just as nephrotoxic as traditional NSAIDs.

Published data show nephrotoxicity rates with COX-2 inhibitors are at least equal to that of traditional NSAIDs. Selecting a COX-2 inhibitor over a traditional NSAID in an attempt to avoid nephrotoxicity is irrational. Risk factors for nephrotoxicity are the same for COX-2 inhibitors and traditional NSAIDs. Patients who are at risk for NSAID nephropathy have decreased renal blood flow and include those with volume depletion (eg, vomiting, diarrhea, diuretic therapy), congestive heart failure, cirrhosis, and chronic kidney disease. COX-2 inhibitors have a lower incidence of gastrointestinal adverse effects when used chronically, but there is a limited role for COX-2 inhibitors in the inpatient setting (eg, continuation of outpatient chronic therapy in patients at high risk for gastrointestinal adverse effects). Misperceptions about the efficacy and safety of COX-2 inhibitors have led to overuse in the inpatient setting. Only celecoxib is listed in the Shands at UF Formulary. Rofecoxib and valdecoxib are not listed in the Formulary. Valdecoxib is nonformulary and not available.

REFERENCES
Who is the P&T Committee?

The Pharmacy and Therapeutics Committee is commonly referred to as “the P&T Committee.” Many physicians have misconceptions about the make-up and nature of this medical staff committee.

The name of the committee contributes to the confusion. The term “pharmacy” in the name may mislead a practitioner into thinking this is a pharmacy committee. It is not.

The P&T Committee is a subcommittee of the Medical Operations Committee, which is the formal line of communication between the medical staff and the hospital on all drug-related matters. Being a medical staff committee, the P&T Committee is primarily physicians. 14 of 18 (77%) P&T committee members are physicians. The 4 non-physicians on the committee are 2 pharmacists, 1 nurse, and a hospital administrator.

The P&T Committee decides which drugs should be listed in the Formulary. The Formulary is a list of drugs that are readily available for use. The drugs listed in the Formulary reflect the opinions of the medical staff as represented by the P&T Committee. The P&T Committee uses an evidence-based medicine approach to determine which drugs should be listed and whether any limitations are needed. Limitations range from endorsing appropriate criteria for use — which can be used for educational purposes — to formal restrictions to specific uses, areas, or other criteria.

The P&T Committee also establishes policies for drug use in the hospital. Again, the P&T Committee uses an evidence-based approach when establishing policies.

A broad range of medical practitioners is useful in establishing these drug-use policies. However, when special input is needed, input is sought from specialty areas or, in some cases, ad hoc committees of physicians with special expertise.

Dr. Ricardo Gonzalez-Rothi chairs the P&T Committee. Dr. Randy Hatton staffs the committee. A list of the P&T members is not generally made available. In the past, this information has been used by drug manufacturers’ sales representatives to lobby for their products. This unwanted solicitation has led to a more limited distribution of the membership list.

If you have any questions or comments about the P&T Committee, please contact us. Correspondence about the P&T Committee can be mailed to Secretary, P&T Committee, PO Box 100316, JHMHSC.