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How to Read a Package Insert

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When you are starting or thinking of starting a new HIV drug, your health care provider will discuss some basic information with you. When you get the prescription filled, you usually receive additional written information. This may be just a brief summary provided by the pharmacy, or you may receive a very detailed "package insert" filled with information provided by the drug manufacturer and approved by the US Food and Drug Administration (FDA).

Each country or region has its own agency that regulates drugs and provides the information that consumers (users) receive with their prescriptions. In India, it is the Central Drugs Standard Control Organization (CDSCO). In Europe, it is the European Medicines Agency (EMA), where the package insert is known as the patient information leaflet (PIL).

If you have a serious medical condition, this is the place to find out whether it is likely to cause a problem if you take this medicine.Package inserts (also known as Prescribing Information) are available for all prescription medications approved by the FDA. Similar information is available for nonprescription medicines and for some herbal medicines and dietary supplements as well.

The package insert can usually be found online on the drug manufacturer's website and is also available in a reference book called the Physicians' Desk Reference (PDR, which also stands for Prescribers' Digital Reference, the book's online version), which you may be able to find at your local library or can access online. The PDR is meant mainly for prescribers. You may not understand some sections but take all your questions and concerns to your HIV provider.

What Is in the Package Insert

The information in a package insert is written in technical language. It is usually very long and can be difficult to understand. However, it is a good idea to look through it, because it lists important information about the drug. If you have any questions, ask your health care provider or pharmacist. You can also ask an educator at your local AIDS service organization.

The package insert follows a standard format for every drug. After some identifying information, such as the drug's brand name, generic name, and year when the drug was first approved by the FDA, most to all of the following sections appear, in this order:

- Highlights of Prescribing Information
- Recent Major Changes
- Indications and Usage
- Dosage and Administration
- Dosage Forms and Strengths
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Use in Specific Populations
- Overdosage
- Description
- Clinical Pharmacology
- Nonclinical Toxicology
- Clinical Studies
- References
- How Supplied/Storage and Handling
- Patient Counseling Information

Package inserts for some HIV drugs begin with "Boxed Warnings," which highlight especially serious (often life-threatening) side effects that have been reported but are rare.

The package insert will most often use the generic name of the drug (the scientific name for its main ingredient or ingredients). Patients usually know a drug by its brand name (the name under which it is sold), so this can be confusing. Also note that a drug's brand name may be different in different countries. For the US, check our HIV Drug Chart (Overview), which lists each drug by brand and generic names, if you have questions. A quick search online using whatever name you have should also bring up the drug's other names (e.g., if what you have is the generic name, most websites that mention the drug will also list its brand name and possible abbreviations).

While there is no specific section of the package insert dedicated solely to women, information that applies to cisgender women (for example, indications for use in pregnant or breastfeeding people, dosing adjustments by weight, drug interactions with birth control pills or hormone replacement therapy) may be found in various sections throughout the package insert.

Here is what you can expect to find in each section:

Highlights of Prescribing Information

This first section is a brief summary of the information that is most important for readers to know. It refers readers to the appropriate section(s) in the package insert for additional, more detailed information.

Recent Major Changes

If there have been changes in the past 12 months to the Boxed Warning, Indications and Usage, Dosage and Administration, Contraindications, and/or Warnings and Precautions for a drug, those changes are detailed in this section.

Indications and Usage

This section lists the uses (indications) for which the drug has been approved by the FDA. All HIV drugs are indicated for use *in combination with* other approved HIV drugs, unless the HIV drug is already a combination pill (e.g., Genvoya). This section will also state if the drug can be used by patients who have taken HIV drugs before (ART-experienced), by patients who have never taken HIV drugs (ART-naive), or by both. It may say what class of drug this is and what other HIV drugs should or should not be taken with it. A detailed description of the clinical studies for this drug will follow and will often include graphs and charts.

Dosage and Administration

This section gives the recommended dosages (doses) of the medicine and may tell you if the drug should be taken with or without food. If the medicine is indicated for more than one use (e.g., to treat HIV and hepatitis B), you may see separate sections for each use. There may also be separate information about dosages for people above and below a certain weight, children, older people, or those with certain medical problems.

Dosage Forms and Strengths

This section describes the drug's color and form (e.g., capsule, ointment). It also lists the strength or amount of medication in that form. Several different strengths and form descriptions may be listed for the same drug.

Contraindications

This section describes situations when the drug should be used with caution or not at all. These are called contraindications. For instance, a medicine should not be prescribed for someone who has had an allergic reaction (hypersensitivity) to the same medication or one that is similar, or for someone who is taking another medicine that has a harmful interaction with this medicine.

This section also may warn health care providers not to prescribe the medicine for people with certain medical conditions because they are at greater risk of dangerous side effects. If you have a serious medical condition, this is the place to find out whether it is likely to cause a problem if you take this

medicine.

This is also the reasoning behind why it is important that you not share your medications with others. Your medication may be harmful to someone else if they have a medical condition that you do not know about.

Warnings and Precautions

This section discusses serious side effects that may occur in people who take this medicine. It does not mean that every side effect will happen to you, but it is important that you pay attention to these warnings, so you will recognize any symptoms that could suggest a serious problem.

If especially severe or life-threatening problems have been found, there may be a "Boxed Warning" on the first page of the package insert. As the name suggests, this information is clearly shown using capital letters surrounded by a black box, so it will not be overlooked.

Before you start taking an HIV drug with warnings that might affect you, your health care provider should explain what the warnings mean and tell you what you should watch for so that any problems can be caught early. Call your provider or pharmacist right away if you ever have a question or concern about a warning or symptoms you experience when taking the drug.

Adverse Reactions

This section lists all the side effects that were reported in people who took this medicine while it was being tested. Side effects, also called adverse reactions, are effects that are different from what the drug was developed to do. These effects are usually grouped according to the body system affected (e.g., liver, skin, stomach), the group of people tested (e.g., adults, children), and perhaps also by how many people reported having each side effect.

You may experience some of the side effects on the list, or none at all. Even the effects listed as being most frequent still only affect a small portion of people who take the medicine.

This list of "adverse events" can look frightening because it includes so many problems, ranging from minor to life-threatening. Remember that this section lists everything that happened to hundreds or thousands of people (and sometimes also animals when the drug was in the early phases of testing). You may experience some of the side effects on the list, or none at all. Even the effects listed as being most frequent still only affect a small portion of people who take the medicine.

Again, you may not experience any of the side effects mentioned. This is very important. It is equally important to tell your health care provider about any symptoms you experience since beginning the new drug.

Your health care provider probably will mention some of the side effects that you should watch for, but every person is different, and it is impossible to tell in advance what you will experience. If you tend to have problems with one body system (such as your skin or stomach), you may be particularly interested in seeing how many people had problems in that area. Many side effects that are troublesome during the first days or weeks after you start taking the medicine may disappear later.

Drug Interactions

This section lists the effects that this medicine may have on other prescription or over-the-counter

medicines you may be taking. This section also might warn that you should not take this medicine with a particular food or other product (such as an antacid).

It is a good idea to look through this section to see if it lists any medicines or other products that you use regularly. Be sure your health care provider knows about all the medications you are taking, even if you only use them occasionally – this includes over-the-counter drugs, prescription drugs, street drugs, supplements, and herbs.

Use in Specific Populations

This section explains what is known about the safety and effectiveness of the drug when used by certain groups. Specifically, it tells whether it is safe for use by nursing or pregnant people, children ("Pediatric Use"), and older people ("Geriatric Use"). Sometimes it may say that not enough information is available. This does not mean that it is unsafe in these groups of people, just that not enough research studies have been done.

Overdosage

This section describes what the results of taking too much of the medicine, or an overdose of the medicine, are likely to be and how an overdose should be treated. This kind of information is mainly useful to medical personnel. If you suspect an overdose of medication, you should contact a poison control center or emergency room right away.

Description

This section gives the chemical name of the drug and a diagram of its chemical makeup. It tells whether it is in tablet form, capsules, liquid, or powder, and how it should be given – by mouth or by injection. It also lists all inactive ingredients, such as fillers, artificial colors, or flavorings. If you have food sensitivities, this is where you can check to see if there are ingredients that may cause you problems.

Clinical Pharmacology

This section tells how the medicine works in the body. It also tells whether studies in different groups of people found any differences in how it works for treatment-experienced patients (people who have taken HIV drugs before), treatment-naïve patients (those who have never taken HIV drugs before), women, children, and elderly people.

This section can be very scientific and may not be written in language most people can understand. It is important that you speak with your provider about any questions or concerns you may have.

This section also describes how the drug is processed in your body and how your body gets rid of it. If you have a special problem, such as kidney or liver disease, this is one of the sections your health care provider will look at while deciding whether to prescribe this type of medicine for you, and if so, how much to give.

Nonclinical Toxicology

This section describes whether the drug tends to cause cancer or can cause cells to change, or mutate. This section may also include information on the drug's effect on fertility (ability to become pregnant). Often, some or all of this information is based on animal studies or studies of human cells (not real people).

Clinical Studies

This section lists the results of studies or clinical trials that were done to show the drug's effectiveness in different groups of people. The results listed often compare this drug to another drug and show the difference in effectiveness between the two. The descriptions of the studies also include information on how long the study was conducted, how many people participated, and basic characteristics of study participants (e.g., age, race, whether they have used HIV drugs before).

References

This section is rarely included and refers the reader to other scientific sources of information.

How Supplied/Storage and Handling

So, if you pick up your prescription from the pharmacy on a hot day, do not leave it in the car while you run other errands!This section lists all available forms of this medicine, including tablets or capsules of various doses and perhaps liquids or powders. Each one is described by color, shape, and markings, so you can be sure which one you are taking. When reading the package insert for Fuzeon (an HIV drug that is injected into the body), this section will talk about how to reconstitute, or mix, the powdered drug with sterile water.

This section also gives storage instructions. This is where you find out whether or not to keep the drug in the refrigerator. It also tells whether pills may be damaged by heat, light, or moisture. For example, there is usually a recommendation against leaving the medicine out in temperatures over 30ºC (86ºF). So, if you pick up your prescription from the pharmacy on a hot day, do not leave it in the car while you run other errands!

Patient Counseling Information

This section lists key information for health care providers to use in talking to patients about how to use the drug. Depending on the drug, this section can include information on correct dosing, likely side effects, and possible drug interactions. When you get a new medicine, this section can be a good one to read. It highlights the information your health care provider should talk over with you. If you have any questions about what is in this section, or you do not remember your provider telling you what is in this section, ask your provider or pharmacist.

How Should I Use the Package Insert?

The package insert is a good source of information to use in addition to instructions your health care provider, nurse, or pharmacist may have given you. It is a good idea to review the package insert for any drug that you are newly taking, and to look at it again if anything about your health changes. If you have any questions after reading it, contact your provider or pharmacist for an explanation.

Additional Resources

Select the links below for additional material related to package inserts.

- How to Read a Drug Label (Drugwatch)
- Do You Read Your Medication’s Package Insert? (Pfizer; video)
- Prescribers' Digital Reference (ConnectiveRx; for providers)
- DailyMed Drug Label Search (US National Library of Medicine)
- Learn About Your Medicines (US Food and Drug Administration)
- How Do I Use Prescription Drug Labeling (US Food and Drug Administration)
- Why You Should Never Throw Away That Medication Package Insert (Banner Health)