

Technician Tutorial: Dispensing Oral Contraceptives

There are many different oral contraceptive pills, or birth control pills, available in both the U.S. and Canada. The primary use of oral contraceptives is to prevent pregnancy by inhibiting ovulation (i.e., the release of an unfertilized egg from the ovaries). Oral contraceptives can also be used to help manage other conditions such as acne, severe premenstrual syndrome (PMS), or menstrual cycle irregularities. The varying levels of natural hormones, mainly estrogen and progestin, regulate the menstrual cycle and ovulation. Oral contraceptives provide steady levels of synthetic (man-made) estrogen and/or progestin. The hormones provided by oral contraceptives disrupt the normal menstrual cycle and ultimately prevent ovulation. If an egg doesn't get released, it cannot get fertilized by sperm and pregnancy can't occur.

Most oral contraceptives contain both an estrogen and a progestin, but some are progestin-only pills, also called "mini pills." Combination pills (those containing an estrogen and progestin) can be monophasic, where the same dose of each ingredient is given throughout the active cycle. Or they can be multiphasic (e.g., biphasic or triphasic), where a different dose is given during each week of the active cycle. These products are meant to mimic the normal hormonal cycle. But they aren't more effective or associated with fewer side effects than monophasic pills. Types of estrogen used in oral contraceptives include ethinyl estradiol (most common) and estradiol valerate (a newer ingredient used in *Natazia* [U.S.]). There are several progestins that are used in oral contraceptives such as desogestrel, levonorgestrel, norethindrone, and drospirenone. Be aware that birth control comes in a number of non-oral dosage forms too. These include a patch (e.g., *Xulane* [U.S.], *Evra* [Canada]), a vaginal ring (e.g., *Annovera*, *NuvaRing*), an intrauterine device (e.g., *Mirena*, *Skyla* [U.S.], *Kyleena* [Canada]), a subdermal rod (*Nexplanon*) and an injection (*Depo-Provera*). Oral contraceptives for emergency use are also available over-the-counter (e.g., *Plan B One-Step* [U.S.], *My Way* [U.S.], *Plan B* [Canada], *Backup Plan Onestep* [Canada]).

Oral contraceptives come in unit-dose packs designating the days of the week. This type of packaging is meant to help prevent missed doses, since a missed dose can increase the risk for pregnancy. In most cases contraceptive ("active pills") will be taken for three weeks, then stopped. Patients will then take "inactive" pills for a week. This is when the patient will have their period. Taking these inactive pills serves as a reminder to take the medication every day. They generally have no therapeutic benefit. However, some products in the U.S. replace the inactive pills with iron tablets. This is because patients may have low iron levels during menstruation because of blood loss. Other products, such as *Seasonale* (Canada), *Jolesse* (U.S.), and *Seasonique*, are taken continuously with an inactive week every three months. These packs have 84 active pills containing hormone and seven inactive pills for a total of 91 pills.

Loestrin Fe 1.5/30
once daily
1 pack
6 refills

Aaryn Moss, a 29-year-old female patient, brings in this new Rx for Loestrin Fe 1.5/30. She tells you that she will wait for the Rx and takes a seat in the waiting area. You see that she has been taking the birth control, Aurovela Fe 1.5/30 [U.S.], for several months. You recognize that even though Aurovela Fe 1.5/30 appears to be a brand name drug, it is the generic equivalent of Loestrin Fe 1.5/30. Before you enter the new prescription you double check to make sure she is in fact out of refills on her old Rx. You notice that

she has one refill left. Since the instructions and drug are the same, you go ahead and refill her Rx for Aurovela and put the new Rx on file for future use. Before you can go any further, the system alerts you that Aurovela is out of stock. You check the shelf and see the spot where it should be is empty. You wonder if you will have to dispense the brand name drug. You go find the pharmacist to ask her what to do next.

What should I consider when inputting prescriptions for oral contraceptives?

Ensure patient profiles are current. Updating the patient's medical history when you receive an oral contraceptive Rx can help the pharmacist screen for problems. For example, smoking may increase the risk of adverse effects with oral contraceptives. And patients who have high blood pressure or certain types of migraines may need to avoid oral contraceptives that have estrogen.

Select the right product. Dispensing the wrong oral contraceptive could cause a patient to have bad effects from fluctuations in hormones such as bleeding, mood changes, or nausea. There are a number of oral contraceptive product names that look and sound very similar. For example, in the U.S., *Junel 1/20* and *Junel Fe 1/20* are easy to confuse. Same with *Microgestin 1/20* and *Microgestin Fe 1/20* or *Loestrin-21 1/20* and *Loestrin Fe 1/20*. In Canada, *Tri-Cyclen*, *Tri-Cyclen Lo*, and *Tricira Lo* look and sound alike, and so do *Yaz* and *Yaz Plus*. This is just a sampling of the many similar brand names that can be easily confused.

The numbers included in the names of oral contraceptives generally signify either the strengths of the hormones (the estrogen and the progestin), or the number of active tablets in a pack. For example, *Loestrin 1.5/30-21* contains norethindrone 1.5 mg and ethinyl estradiol 30 mcg, and there are 21 active tablets in the pack. Another example is *Blisovi 24 Fe* (U.S.), which has 24 active tablets in the pack, and an iron supplement for the remaining four tablets. Iron is represented by "Fe," its chemical symbol. As a rule of thumb, when you see the numbers 21 or 28 in the name of the drug, this is usually representing the number of pills in the pack. Numbers on either side of a "/" usually represent the strength, but not always. The lower dose typically represents the progestin component and the higher dose the estrogen component. With multiphasic pills you may see numbers next to the drug name representing the number of days of different doses of active pills. For example, *Ortho-Novum 7/7/7* (U.S.) contains the following strengths of active pills:

- 7 days of 0.5 mg norethindrone and 35 mcg ethinyl estradiol
- 7 days of 0.75 mg norethindrone and 35 mcg ethinyl estradiol
- 7 days of 1 mg norethindrone and 35 mcg ethinyl estradiol

Generic substitution. Generic substitution can be tricky for oral contraceptives. The term "generic substitution" refers to the process of filling a prescription for a brand-name drug with an equivalent generic medication. In the U.S., generic substitution is regulated at the state level, so each state has its own generic substitution laws. In Canada, generic substitution is regulated by provinces. Generic substitution laws allow a pharmacist to dispense a generic equivalent rather than a brand-name drug when the brand name is written on the Rx unless the prescriber has specified otherwise.

In the U.S., the Food and Drug Administration (FDA) publishes a book that is used as the standard by which many states allow generic substitution. It is called the "Orange Book" or more formally, *Approved Drug Products with Therapeutic Equivalence Evaluations*. The Orange Book can be accessed online at the following website (<http://www.accessdata.fda.gov/scripts/cder/ob/>). As its formal title implies, the Orange Book contains ratings that show whether two drugs are "therapeutically equivalent," or expected to have the same safety and effectiveness.

One thing that's confusing about generics for oral contraceptives is that they often have names that sound like brand names instead of generic names. For example, *Nikki* (U.S.) and *Loryna* (U.S.) are listed as generics for *Yaz* in the Orange Book. A *Yaz* Rx can be filled with either of these products in most states.

It can be difficult to determine which oral contraceptives are equivalent. Usually it's okay to rely on your computer system to automatically select the appropriate generic when you enter the brand-name drug. But sometimes this might not be possible. For example, if you enter the generic name first instead of the brand name, some systems might not show you other equivalent products. Or, if there's a new generic drug manufacturer it might not be loaded in the system yet. The product may be there, but it might not be linked to the brand. If you're unsure about whether one product can be substituted for another, double-check with the pharmacist.

We have charts of available hormonal contraceptives in the U.S. and Canada. In our charts, products are grouped together by the same hormone content. However, this grouping is **not** meant to indicate which products can be substituted for each other. Review our chart, *Comparison of Oral Contraceptives and Non-Oral Alternatives* (U.S. Subscribers); (Canadian subscribers) to get familiar with the different products available.

Days' supply. It's important to enter the correct days' supply of oral contraceptives into the computer. When you dispense most packs, you enter a 28-day supply. (There are some exceptions, such as *Seasonique*, etc, which are discussed below.) If a patient gets more than one pack, you'll need to adjust the days' supply appropriately, to 84 days for three packs, for example.

Keep in mind, the prescriber might prescribe a 28-day pack, but instruct the patient to take only the 21 active tablets, then start a new pack right away (i.e., skip the inactive pills). This is called "continuous use" or "continuous contraception." Eliminating the hormone-free days will prevent a patient from having a menstrual period. Fewer periods can minimize problems such as menstrual migraine, low iron from heavy blood loss, and endometriosis. Be on the look-out for scenarios like this with directions that say, "Use as directed." The pharmacist may want to verify the exact directions for insurance auditing purposes. In this case, the 28-day pack is only a 21-day supply since the patient will skip the seven inactive pills. You'll need to enter a 21-day supply into the computer to prevent an early refill flag from popping up with the next refill. Be aware that some insurers may not cover a 21-day supply. In this case you may need to call the insurer for an override or prior authorization request.

Some products only have 21 active pills without any inactive or iron pills. As previously discussed, you may be able to identify that a drug has only 21 pills by seeing the number 21 in the drug name. Alternatively, "21-day supply" is usually indicated on the package itself if you need to double check.

Some products, such as *Seasonale* (Canada), *Seasonique*, and *LoSeasonique* (U.S.) are packaged differently than most oral contraceptives. Packs of these products contain 91-day supplies. Similar to situations where a patient skips placebo pills to prevent their period, these products are actually meant to reduce the number of periods a patient has. *Seasonale* (Canada), *Seasonique*, and *LoSeasonique* (U.S.) allow for only four menstrual periods each year.

Drug-drug interactions. Some drugs can cause problems with oral contraceptives. Antiseizure drugs such as phenytoin, phenobarbital, or carbamazepine and "rifamycin" antibiotics such as rifampin or rifabutin may make oral contraceptives less effective. It's because these drugs increase the breakdown of oral contraceptives. In contrast, some drugs can have their efficacy decreased by oral contraceptives. This includes drugs like lamotrigine and fosamprenavir (*Lexiva* [U.S.], *Telzir* [Canada]). It's generally recommended that most oral contraceptives be avoided in patients taking these drugs.

There's still a lot we don't know about how other drugs might impact the efficacy of oral contraceptives and vice versa. A lot of what we know is based on theories and our knowledge of how drugs work in the body. This sometimes leads to controversy when determining if patients should take additional steps to prevent pregnancy. For example, you may see drug interaction warnings for oral contraceptives and various antibiotics such as amoxicillin, azithromycin, or ciprofloxacin. This is based on the theory that antibiotics can kill the bacteria responsible for keeping oral contraceptives in the body. However, the clinical significance of this hasn't been proven. Nonetheless, pharmacists usually err on the side of caution when antibiotics need to be used in patients on oral contraceptives. You may hear pharmacists recommend that patients use back-up contraception (e.g., condom, diaphragm) or abstinence from sex during antibiotic therapy and for a week after the last dose.

It's also possible for dietary supplements and herbals to interact with oral contraceptives. An important example is St. John's wort. It may reduce the effectiveness of oral contraceptives, resulting in irregular bleeding and unintended pregnancy. Pharmacists may want to counsel the patient to avoid this supplement.

Alert the pharmacist to any drug-drug interaction flags with oral contraceptives so they can counsel the patient as appropriate. Since the risk of the interaction can be an unplanned pregnancy, it's important to err on the side of caution. Especially since the same drug that might decrease the efficacy of oral contraceptives may also be unsafe during pregnancy. This is the case with the antiseizure meds previously discussed.

The pharmacist tells you that the pharmacy recently got a new supplier for the generic version of Loestrin Fe 1.5/30. The new generic that the pharmacy is dispensing goes by the name of Junel Fe 1.5/30. You find this drug on the shelf and edit the refill with the new NDC. The system recognizes that Aurovela and Junel are generic equivalents and allows you to make this change. As you attempt to continue to process the Rx, you get an insurance rejection indicating that the refill is too soon. You notice Aaryn should still have at least eight days left on the Rx she filled about three weeks ago. You call her over to let her know. She tells you that her doctor just approved her to take this medication continuously, skipping the week of iron pills and starting a new pack after finishing the last pill in the third week. You know that patients sometimes take birth control pills continuously to avoid having menstrual periods, so you alert the pharmacist and she double-checks with Aaryn. Aaryn confirms that yes, that's the case. She has bad headaches when she gets her period and her doctor thinks continuous use of her birth control pills might help.

You call the insurance company and they indicate that they will cover the early refill but that you first need a new Rx from the doctor with directions indicating that the patient should take the pills continuously. You let the pharmacist know. Since the new Rx Aaryn brought in said to take once daily and dispense one pack, the pharmacist will have to call to confirm the change in the Rx with the prescriber. The pharmacist eventually hands you a new Rx that says the following:

*Loestrin Fe 1.5/30
Take 1 active pill daily for three weeks,
then start your next pill pack
1 pack for a 21-day supply
6 refills*

Although you still get an insurance rejection saying refill too soon, you are able to enter an override code from the insurance company indicating that the prescriber was consulted.

What types of things should be considered when dispensing oral contraceptives?

Select the right product. Once again, similar brand names could easily lead to selection of the wrong product from the shelf. Some product names are so similar and can differ by the presence or absence of just a couple of letters or numbers. Always double-check the product you choose from the shelf with the Rx label. For example, in the U.S., *Junel*, the generic for *Loestrin*, is available as *Junel 1/20*, *Junel FE 1/20*, *Junel 1.5/30*, and *Junel FE 1.5/30*. Other examples include *Sprintec* (U.S.), *Tri-Lo-Sprintec* (U.S.), and *Tri-Sprintec* (U.S.) and *Ortho-Cyclin* (U.S.), *Ortho Tri-Cyclin* (U.S.), and *Ortho Tri-Cyclin Lo* (U.S.). Strengths are also very important to double check since the same product name may come in multiple strengths (e.g., *Nortrel 1/35-21* [U.S.], *Nortrel 0.5/35* [U.S.], and *Nortrel 7/7/7* [U.S.]; *Brevicon 0.5/35* [Canada] and *Brevicon 1/35* [Canada]). And keep in mind, even some products with dissimilar names have similar packaging that could lead to selection of the wrong one. Use strategies such as placement of shelf tags and labels to help differentiate these.

Place the label correctly. Make sure you know how you're expected to label oral contraceptives in your pharmacy. Some pharmacists might want the label to be placed on the outside of the foil pouch or wrapping. Other pharmacists might prefer that you actually open up and label the pack directly. When labeling a pack, there is usually a designated space marked for the Rx label. If the pack doesn't designate a space, make sure that wherever you place the label it isn't covering important information.

You make sure to select the right product from the shelf by double checking the NDC number. You know that the pharmacist prefers that you open the package and apply the label directly to the slip designed to hold the pills. You place the pills into the slip along with the patient package insert.

Are there any special labeling requirements for oral contraceptives?

Patient package insert. FDA requires that a patient package insert (PPI) be dispensed with oral contraceptives. The patient package insert has important information about risks from oral contraceptives, and guidance on how to take them properly. Patient package inserts are provided by the manufacturer and included in the product packaging. If you open the packaging and label the pack directly, then make sure to include the enclosed patient package insert with the drug.

Auxiliary labels. In some pharmacies, auxiliary labels may automatically print out for oral contraceptives. Automatically generated auxiliary labels may warn the patient that some drugs can cause birth control to be less effective. Or the labels may caution patients to avoid smoking while taking birth control (because this can increase the risk of adverse effects). Make sure to apply these auxiliary labels to the package so that patients have these reminders. Another label you may see warns patients not to take oral contraceptives if they are pregnant. This is because the risk of taking this medication during pregnancy outweighs the benefit. Plus, it isn't likely to be needed.

Recall that there can be several different equivalent generic products disguised as what might look like different brand names. Apply a "same medication - color size, or shape may be different" label when generic manufacturers change. This is especially important for oral contraceptives because the medication will have a completely different name.

You make sure to stick all of the auxiliary labels that automatically printed out next to the Rx label. You also add a label to let Aaryn know that this is the same medication, but it will look different. Now the Rx is ready for the pharmacist to check.

What if a patient asks about a missed dose?

If a patient misses any doses of an oral contraceptive, the pharmacist's advice will depend on a number of things including the product being used, how long since the dose was missed, how many doses have been

missed, and when during the menstrual cycle the dose was missed. Alert the pharmacist if a patient asks about a missed dose. Missing oral contraceptive doses can have consequences such as irregular bleeding and unintended pregnancy. Patients may need to use back-up contraception for a time and even emergency contraception in some cases. Advice on what to do for each product is included in the patient package insert.

What are emergency contraceptives?

Products such as *Plan B One-Step* (U.S.), *Prevenza* (U.S.), *My Way* [U.S.], *Plan B* (Canada), *Contingency One* (Canada) are called emergency contraceptives or sometimes the “day after pill” or “morning after pill.” They all contain a single pill with 1.5 mg of the progestin levonorgestrel. Emergency contraceptives can be taken to prevent pregnancy after unprotected sex or when there is a known or suspected contraceptive failure (e.g., broken condom). These drugs are not effective in terminating an existing pregnancy, nor do they protect against sexually transmitted diseases including HIV infection. They should be taken as soon as possible after unprotected intercourse and no longer than 72 hours after.

These products are available OTC regardless of the patient’s age. If you work in the U.S., you may recall a time where some products could only be sold OTC to people 17 years of age and older (e.g., *Plan B* and other products containing two 0.75 mg pills of levonorgestrel versus the current products containing one pill with 1.5 mg of levonorgestrel). These products are no longer being marketed and you shouldn’t encounter them anymore. Alert the pharmacist if you notice a patient buying OTC emergency contraceptives frequently. Frequent use isn’t intended, and the pharmacist may want to take the opportunity to speak with the patient about using a reliable birth control method instead.

I work in a state that allows pharmacists to prescribe birth control. How can I help out?

In the U.S., states such as California, Oregon, and West Virginia have passed laws that allow pharmacists to prescribe birth control to patients. Even if your state doesn’t currently have a law like this, it may pass one in the future. Usually states set an age requirement for this service. For example, in Oregon patients must be 18 years of age or older if the pharmacist is prescribing a new Rx. Refills could be prescribed to younger patients, but only with proof of a previous Rx from a prescriber. You can help pharmacists verify the patient’s age by requesting photo identification to help get the process started. Once you know that the patient is the right age to receive the service, a few other things need to be confirmed. To make sure a patient is eligible, there will typically be a screening questionnaire. Similar to an immunization screening form, this questionnaire gathers information on the patient’s medical conditions and current medications. The questions are targeted to help the pharmacist determine if the patient can safely use an oral contraceptive. As previously mentioned, some conditions and medications could be risky with oral contraceptives, so this screening questionnaire is important for patient safety. You can help make sure the patient receives the screening questionnaire and fills it out completely.

You can also help set a patient’s expectations when they request this service. Similar to immunizations, pharmacists will often have to fit this into their normal workflow. Let the patient know about how long it should take for the pharmacist to see them. Take the initiative to get involved with scheduling appointments, making phone calls to remind patients of upcoming appointments, or billing for the patient visit. Get involved with marketing this service. Provide fliers and explain the service to patients filling an Rx for birth control or purchasing an emergency contraceptive. Your pharmacist and your patient will appreciate your help.

Prepared by the Editors of Therapeutic Research Center (361080).

Cite this document as follows: Technician Tutorial, Dispensing Oral Contraceptives. Pharmacist’s Letter/Pharmacy Technician’s Letter. October 2020.

“Cheat Sheet” for Dispensing Oral Contraceptives

What types of things should I consider when inputting prescriptions for oral contraceptives?

- Update profile with medical conditions, smoking status, etc.
- Select the right product. Stay especially alert for oral contraceptives that have similar names. Be mindful of the numbers in the names, which generally signify hormone strength and number of pills.
- Generic substitution. Follow your state’s laws. Keep in mind that some generic oral contraceptives have names that sound like brands.
- Days’ supply. This will usually be 28 days, but may need to be adjusted, such as if a patient receives more than one pack at a time or uses the contraceptive continuously.
- Drug-drug interactions. Being mindful of these is very important, considering that the consequence can be unintended pregnancy.

What types of things should be considered when dispensing oral contraceptives?

- Product selection. When selecting oral contraceptives from pharmacy shelves, stay alert for similar names and also for look-alike packaging, such as when products are made by the same manufacturer.
- Label placement. Follow the pharmacist’s preference for label placement. Ensure you don’t cover up any important info on the package.

Are there any special labeling requirements for oral contraceptives?

- Patient package inserts. The FDA requires these to be dispensed along with oral contraceptives. They are in the product packages and let patients know about associated risks and also how to take their med.
- Auxiliary labels. You may also need to apply a “same medication – color, size, or shape may be different” label when generic manufacturers change. Plus, these additional labels may also print out along with oral contraceptive labels:
 - A warning that some drugs can cause birth control to be less effective.
 - Advice to avoid smoking while taking birth control.
 - A warning not to take oral contraceptives during pregnancy.

What if a patient asks about a missed dose?

- Notify the pharmacist so they can advise the patient. This may include a recommendation to use back-up contraception to help prevent unintended pregnancy.

What are emergency contraceptives?

- These help prevent pregnancy following unprotected sex. They are a single pill and should be taken within 72 hours after the fact.

I work in a state that allows pharmacists to prescribe birth control. How can I help out?

- After checking a patient’s ID to verify that they meet your state’s age requirement, you can present them with a screening questionnaire, schedule a time with a pharmacist, etc. Think of it as similar to what you’d do for patients who need to receive vaccines.

[October 2020; 361080]