

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ALESSE[®] 21 and ALESSE[®] 28

100 mcg Levonorgestrel and 20 mcg Ethinyl Estradiol Tablets

Read this carefully before you start taking **ALESSE 21** and **ALESSE 28** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ALESSE 21 and ALESSE 28.

Serious Warnings and Precautions

- Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age particularly in women older than 35 years of age, who use hormonal birth control. The risk also increases with the number of cigarettes smoked. For this reason, women who smoke and are over 35 years of age should not use ALESSE.
- Birth control pills DO NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS.
- For protection against STIs, you must use latex or polyurethane condoms AND take your birth control pills.

What is ALESSE used for?

- To prevent pregnancy.
- To treat moderate acne in women 14 years of age and older who are able to use birth control pills, desire birth control and have achieved menarche. Your first menstrual period is called menarche.

How does ALESSE work?

ALESSE is a birth control pill (oral contraceptive). It is considered to be a combination oral contraceptive. This is because it contains two female sex hormones: levonorgestrel and ethinyl estradiol. Combination birth control pills work by:

- Stopping the monthly release of an egg by the ovaries
- Changing the endometrium (lining of the womb) and mucus produced by the cervix (opening of the uterus).

Effectiveness of Birth Control Pills

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

The chance of becoming pregnant increases with incorrect use.

Other Ways to Prevent Pregnancy

Other methods of birth control are available to you. They are usually less effective than birth control pills. When used properly, however, other methods of birth control are effective enough for many women.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported rates represent the number of women out of 100 who would become pregnant in one year.

Reported Pregnancies per 100 Women per Year:

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Condom with spermicidal foam or gel	1 to 6
Mini-pill	3 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. This does not apply to IUDs since they are implanted in the uterus. Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

What are the ingredients in ALESSE?

Medicinal ingredients: Levonorgestrel and Ethinyl Estradiol

Non-medicinal ingredients: hydroxypropylmethylcellulose, lactose, magnesium stearate, microcrystalline cellulose, polacrillin, polyethylene glycol, red iron oxide and titanium dioxide. It may also contain montanglycol wax (wax E pharma).

Each inactive tablet (in ALESSE 28) contains:

- hydroxypropylmethylcellulose, lactose, magnesium stearate, microcrystalline cellulose, montanglycol wax (wax E pharma), polacrillin, polyethylene glycol and titanium dioxide
- OR
- hydroxypropylmethylcellulose, lactose, maize starch, magnesium stearate, polyethylene glycol and titanium dioxide

ALESSE comes in the following dosage forms:

ALESSE are available in a 21-day regimen (ALESSE 21) and a 28-day regimen (ALESSE 28)

ALESSE 21: Each package contains 21 pink tablets. Each pink tablet contains 100 mcg levonorgestrel and 20 mcg ethinyl estradiol.

ALESSE 28: Each blister pack contains 21 pink tablets and 7 white tablets. Each pink tablet contains 100 mcg levonorgestrel and 20 mcg ethinyl estradiol. The white tablets are “reminder” tablets (they do not contain hormones).

Do not use ALESSE if you have or have had any of the following conditions:

- History of or actual heart attack, chest pain (angina pectoris) or stroke;
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), eyes or elsewhere;
- Hereditary or acquired blood clotting disorders;
- Known or suspected cancer of the breast, sex organs, or certain estrogen-dependent cancers;
- Unexplained vaginal bleeding (until a diagnosis is reached by your healthcare professional);
- Partial or complete loss of vision or other vision problems caused by vascular disease (blood vessel disease of the eye);
- History of or actual liver disease or history of or actual benign or malignant liver tumor;
- Jaundice (yellowing of the skin and eyes) or liver disease if still present;
- Heart valve or heart rhythm disorders that may be associated with formation of blood clots;
- Diabetes affecting your circulation;
- Migraines (current or history) with neurological symptoms such as aura (visual or sensory disturbance);
- Uncontrolled high blood pressure;
- Hypersensitivity(allergy) to any of the components of ALESSE (levonorgestrel and ethinyl estradiol tablets) (see *What are the ingredients in Alesse*);
- Known or suspected pregnancy. Birth control pills should never be taken if you think you are pregnant. They will not prevent the pregnancy from continuing;
- Pancreatitis associated with severe hypertriglyceridemia (too many triglycerides (fats) in your blood) (current or history). Pancreatitis is the inflammation of the pancreas, marked by abdominal pain, whereas severe hypertriglyceridemia is a very high level of triglycerides in the blood, and may show no symptoms.
- Are using anti-viral medications to treat Hepatitis C Virus (HCV) which contain combination of ombitasvir, paritaprevir, ritonavir and dasabuvir with or without ribavirin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALESSE. Talk about any health conditions or problems you may have, including if you:

- Have Breast conditions.
 - A strong family history of breast cancer.
 - Breast disorders including pain, discharge from the nipples, thickenings, or lumps.
- Have cervical cancer.
- Have liver tumors.
- Have Diabetes.
- Have high blood pressure.
- Have abnormal levels of fats in the bloodstream (high cholesterol or triglycerides).
- Cigarette Smoke.
- Have heart or kidney disease.
- Have epilepsy/seizures.
- Have a history of depression.
- Have fibroid tumours of the uterus.
- Have gallbladder or pancreatic disease.
- Have a history of liver disease or jaundice.
- Have a family history of blood clots, heart attacks or strokes.
- May be pregnant or breast feeding.
- Have systemic lupus erythematosus.

- Have inflammatory bowel disease such as Crohn’s disease or ulcerative colitis.
- Have haemolytic uremic syndrome.
- Have sickle cell disease.
- Have problems with the valves in your heart and/or have irregular heart rhythm.
- Wear contact lenses.
- Have Hepatitis C.

If you see a different healthcare professional, inform him or her that you are using ALESSE.

Tell your healthcare professional if you are scheduled for any laboratory tests. This is because certain blood tests may be affected by hormonal oral contraceptives.

Also tell your healthcare professional if you are scheduled for **MAJOR** surgery, recent delivery, or second-trimester abortion. You should tell your healthcare professional about stopping the use of ALESSE four weeks before major surgery and not using ALESSE for a time period after surgery or during prolonged bed rest.

ALESSE should be used only under the supervision of your healthcare professional. Your healthcare professional will schedule regular follow-up visits to identify side effects caused by ALESSE. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your healthcare professional three months or sooner after the initial examination. Afterward, visit your healthcare professional at least once a year.

Use ALESSE only on the advice of your healthcare professional and carefully follow all directions given to you. You must use the birth control pill exactly as prescribed. Otherwise, you may become pregnant.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Certain drugs may interact with birth-control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. You may also need to use a non-hormonal method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective. Your healthcare professional will tell you if you need to use a non-hormonal method of birth control.

The following may interact with ALESSE:

- drugs used for epilepsy such as barbiturates (e.g. phenobarbital) and phenytoin, primidone, topiramate, carbamazepine.
- certain drugs used in the treatment of tuberculosis (eg. rifampicin, rifabutin).
- drugs used for HIV or AIDS such as ritonavir.
- herbal products containing St. John’s Wort (*Hypericum perforatum*).
- antibiotics (e.g. penicillins, tetracyclines) for infectious diseases.
- Cyclosporine.
- antifungals (griseofulvin).
- cholesterol-lowering drugs (eg. clofibrate).
- antihypertensive drugs (for high blood pressure).
- antidiabetic drugs and insulin (for diabetes).
- prednisone.

- sedatives and hypnotics (eg, benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate).
- antidepressants (e.g. clomipramine).
- other drugs such as phenylbutazone, analgesics, modafinil, troleandomycin, Vitamin E and Vitamin B12.
- anti-viral hepatitis C virus (HCV) medicinal products such as ombitasvir, paritaprevir, ritonavir and dasabuvir, with or without ribavirin.

Please inform your healthcare professional and pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also tell any other healthcare professional or dentist who prescribes another drug (or the dispensing pharmacist) that you use ALESSE. They can tell you if you need to use an additional method of contraception and if so, for how long.

This is not a complete list of possible drug interactions with ALESSE. Talk to your healthcare professional for more information about drug interactions.

How to take ALESSE?

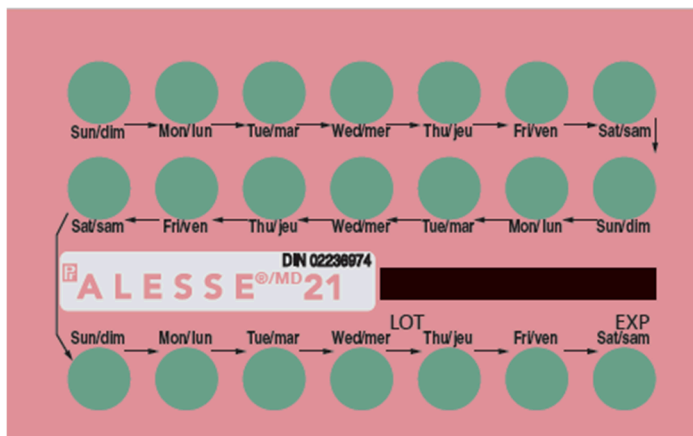
Usual dose:

1. READ THESE DIRECTIONS

- Before you start taking your pills, and
- Any time you are not sure what to do.

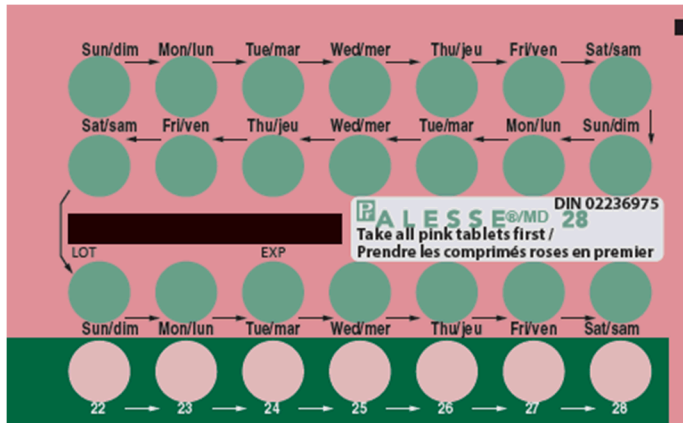
2. LOOK AT YOUR PILL PACK to see if it has 21 or 28 pills:

- 21-Pill Pack: 21 active pills (with hormones) taken daily for three weeks, and then no pills taken for one week;



Or

- 28-Pill Pack: 21 active pills (with hormones) taken daily for three weeks, and then seven "reminder" pills (no hormones) taken daily for one week.



3. You may wish to use a second method of birth control (e.g. latex condoms and spermicidal foam or gel) for the first seven days of the first cycle of pill use. This will provide a back-up in case you forgot to take your pills while you are getting used to taking them everyday.
4. **When receiving any medical treatment, be sure to tell your healthcare professional that you are using birth control pills.**
5. Many women have spotting or light bleeding or may feel sick to their stomach during the first three months on the pill. If you do feel sick, do not stop taking ALESSE. The problem will usually go away. If it does not go away, check with your healthcare professional or clinic.
6. Missing pills also can cause some spotting or light bleeding, even if you make up the missed pills. You also could feel a little sick to your stomach on the days you take two pills to make up for missed pills.
7. If you miss pills at any time, you could get pregnant. The greatest risks for pregnancy are:
 - when you start a pack late or
 - when you miss pills at the beginning or at the very end of the pack.
8. Always be sure you have ready:
 - Another kind of birth control (such as latex condoms and spermicidal foam or gel) to use as a back-up in case you miss pills, and
 - An extra pack of pills.
9. If you experience vomiting or diarrhea, or if you take certain medicines, such as antibiotics, your pills may not work as well. Use a back-up method, such as latex condoms and spermicidal foam or gel, until you can check with your healthcare professional or clinic.
10. If you forgot more than one pill two months in a row, talk to your healthcare professional or clinic about how to make pill-taking easier or about using another method of birth control.
11. If your questions are not answered here, call your healthcare professional or clinic.

When to start the first pack of pills

BE SURE TO READ THESE INSTRUCTIONS:

- before you start taking your pills, and
- any time you are not sure what to do.

Decide with your healthcare professional or clinic what is the best day for you to start taking your first pack of pills. Your pills may be either a 21-day or a 28-day type.

A. 21-DAY COMBINATION

With this type of birth control pill, you are on pills for 21 days and off pills for seven days. You must not be off the pills for more than seven days in a row.

1. **The first day of your menstrual period (bleeding) is day 1 of your cycle.** Your healthcare professional may advise you to start taking the pills on Day 1, on Day 5, or on the first Sunday after your period begins. If your period starts on Sunday, start that same day. If ALESSE tablets are started after day 1 of your first cycle or postpartum (the period of time after childbirth) you should not rely on ALESSE to prevent pregnancy until the first 7 active tablets are taken for seven consecutive days. Non-hormonal methods of contraception (such as latex condoms and spermicidal foam or gel) should be used for the first 7 days of tablet taking.
2. Take one pill at approximately the same time every day for 21 days, then take no pills for seven days. Start a new pack on the eighth day. You will probably have a period during the seven days off the pill. (This bleeding may be lighter and shorter than your usual period).

Two ways to remember in what order to take the pills

1. Follow the days of the week (as shown above the pills).
2. Always finish the pink tablets before going on to the week when you are off pills.

B. 28-DAY COMBINATION

With this type of birth control pill, you take 21 pills that contain hormones and seven pills that contain no hormones.

1. **The first day of your menstrual period (bleeding) is day 1 of your cycle.** Your healthcare professional may advise you to start taking the pills on Day 1, on Day 5, or on the first Sunday after your period begins. If your period starts on Sunday, start that same day.
If you start taking ALESSE tablets after day 1 of your first cycle or postpartum (the period of time after childbirth) you should not rely on ALESSE to prevent pregnancy until the first 7 active tablets are taken for seven consecutive days. Non-hormonal methods of contraception (such as latex condoms and spermicidal foam or gel) should be used for the first 7 days of tablet taking.
2. Take one pill at approximately the same time every day for 28 days. Begin a new pack the next day, **NOT MISSING ANY DAYS**. Your period should occur during the last seven days of using that pill pack.

Two ways to remember in what order to take the pills.

1. Follow the days of the week (as shown above the pills).
2. Always finish the pink tablets before going on to the white numbered pills.

What to do during the month

1. Take a pill at approximately the same time every day until the pack is empty.
2. Try to associate taking your pill with some regular activity such as eating a meal or going to bed.
3. Do not skip pills even if you have bleeding between monthly periods or feel sick to your stomach (nausea).
4. Do not skip pills even if you do not have sex very often.
5. When you finish a pack

- 21 pills

Wait seven days to start the next pack. You will have your period during that week.

- 28 pills

Start the next pack ON THE NEXT DAY. Take one pill every day. Do not wait any days between packs.

Overdose:

Overdosage may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, and fatigue/drowsiness. Withdrawal bleeding may occur in females.

If you think you, or a person you are caring for, have taken too much ALESSE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

WHAT TO DO IF YOU MISS PILLS

Birth control pills may not be as effective if you miss pills. The following chart outlines the actions you should take if you miss one or more of your birth control pills. Match the number of pills missed with the appropriate starting time for your type of pill pack.

SUNDAY START	OTHER THAN SUNDAY START
Miss One Pill	Miss One Pill
Take it as soon as you remember and take the next pill at the usual time. This means that you might take two pills in one day.	Take it as soon as you remember and take the next pill at the usual time. This means that you might take two pills in one day.

<p>Miss Two Pills in a Row</p> <p>First two weeks</p> <ol style="list-style-type: none"> 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. <p>Third week</p> <ol style="list-style-type: none"> 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the rest of the pack and start a new pack that day. 3. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. 4. You may not have a period this month. <p>If You Miss Two periods in a Row, Call Your healthcare professional or Clinic.</p>	<p>Miss Two Pills in a Row</p> <p>First two weeks</p> <ol style="list-style-type: none"> 1. Take two pills the day you remember and two pills the next day. 2. Then take one pill a day until you finish the pack. 3. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. <p>Third week</p> <ol style="list-style-type: none"> 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. 3. You may not have a period this month. <p>If You Miss Two Periods in a Row, Call Your healthcare professional or Clinic.</p>
<p>Miss Three or More Pills in a Row</p> <p>Anytime in the cycle</p> <ol style="list-style-type: none"> 1. Keep taking one pill a day until Sunday. 2. On Sunday, safely discard the rest of the pack and start a new pack that day. 3. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. 4. You may not have a period this month. <p>If You Miss Two periods in a Row, Call Your healthcare professional or Clinic.</p>	<p>Miss Three or More Pills in a Row</p> <p>Anytime in the cycle</p> <ol style="list-style-type: none"> 1. Safely dispose of the rest of the pill pack and start a new pack that same day. 2. Use a nonhormonal back-up method of birth control if you have sex in the seven days after you miss the pills. 3. You may not have a period this month. <p>If You Miss Two Periods in a Row, Call Your healthcare professional or Clinic.</p>

NOTE: 28-DAY PACK - If you forget any of the seven "reminder" pills (without hormones) in Week 4, just safely dispose of the pills you missed. Then keep taking one pill each day until the pack is empty. You do not need to use a back-up method.

Always be sure you have on hand:

- a non-hormonal back-up method of birth control (such as latex condoms and spermicidal foam or gel) in case you miss pills, and
- an extra, full pack of pills.

IF YOU FORGET MORE THAN ONE PILL TWO MONTHS IN A ROW, TALK TO YOUR HEALTHCARE PROFESSIONAL OR CLINIC about ways to make pill-taking easier or about using another method of birth control.

What are possible side effects from using ALESSE?

These are not all the possible side effects you may have when taking ALESSE. If you experience any side effects not listed here, tell your healthcare professional.

- There may be tenderness of the breast, nausea, and vomiting. Some users will experience weight gain or loss. Many of these side effects occurred with high-dose combination birth control pills. These side effects are less common with the low-dose pills prescribed today.
- Unexpected vaginal bleeding or spotting and changes in the usual menstrual period may also occur. These side effects usually disappear after the first few cycles. This does not mean that you should stop taking your birth control pills. Unless you have more serious side effects, a decision to stop using the pill or to change the brand of pill should be made only after three consecutive months of use. This decision should be made with your healthcare professional. You may develop high blood pressure that may require stopping the use of birth control pills. If you develop high blood pressure, talk to your healthcare professional.

Other side effects may include:

- growth of pre-existing fibroid tumours of the uterus.
- an increase or decrease in hair growth, sex drive and appetite.
- skin pigmentation.
- headaches.
- abnormal liver test, nausea, vomiting, severe pain or lump in the abdomen.
- rash and/or
- vaginal infections.

Sometimes, there is a need to change contact lens prescription or an inability to use contact lenses. Your menstrual period may be delayed after stopping birth control pills. There is no evidence that the use of the pill leads to a decrease in fertility. It is wise to delay starting a pregnancy for one menstrual period after stopping birth control pills.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Sharp pain in the chest, coughing blood, or sudden shortness of breath			√
Pain or swelling in the leg			√
Crushing chest pain or heaviness			√
Sudden severe or worsening headache or vomiting, dizziness or fainting, disturbance of vision or speech, or weakness or numbness in an arm or leg			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Sudden partial or complete loss of vision			√
Abnormal liver test and/or, nausea, vomiting, severe pain or lump in the abdomen		√	
Persistent sad mood			√
Yellowing of the skin or eyes (jaundice)			√
Unusual swelling of the extremities		√	
Breast lumps		√	
Unexpected (Abnormal) vaginal bleeding		√	

This is not a complete list of side effects. For any unexpected effects while taking ALESSE, contact your healthcare professional or pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15-30°C).

ALESSE 21 and ALESSE 28 should be protected from light once opened using the protective covering provided.

Keep out of reach of children and pets.

If you want more information about ALESSE 21 and ALESSE 28:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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