A meta-analysis of 54 studies found a small increase in the frequency of breast cancer diagnosis for women who were oral contraceptive users compared to women who were non-users. In the age group 35 to 44, the estimated risk of developing breast cancer for users was about 2.2 times that for non-users. The risk of breast cancer was also greater with oral contraceptives containing higher doses of estrogens and used for a longer period of time.

**FUTURE DEVELOPMENTS**

Further research is needed to fully understand the risks and benefits of oral contraceptives and to improve their safety and efficacy. It is important to continue to develop new methods of birth control that are effective, safe, and acceptable to users.

**REFERENCES**


**APPENDIX**

A review of the effectiveness and safety of oral contraceptives is provided in the following tables and figures.
In addition, combination oral contraceptives may decrease the amount and quality of your milk. If possible, do not use combination oral contraceptives while breast feeding. You should use another method of contraception since breast feeding provides partial protection from becoming pregnant and this partial protection decreases significantly as you breast feed for longer periods of time. You should consider switching combination oral contraceptives only after you have weaned your child completely.

3. Laboratory tests

- Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include diuretics, drugs used for epilepsy such as carbamazepine (for example, phenothiazine), anticonvulsants such as lamotrigine (Tagamet is one brand of this drug), phenytoin (Dilantin is one brand of this drug), phenobarbital (Luminal is one brand of this drug), and possibly certain antibiotics. Minimal contraceptive interactions may occur with lamotrigine (LAMICTAL®), an anticonvulsant used for epilepsy. This may increase the risk of seizures so your healthcare professional may need to adjust the dose of lamotrigine. You may need to use additional contraception when you take drugs which can make oral contraceptives less effective.

4. Sexually transmitted diseases

- Oral contraceptives may decrease the amount and quality of your milk. If possible, do not use combination oral contraceptives while breast feeding. Breast feeding provides partial protection from becoming pregnant and this partial protection decreases significantly as you breast feed for longer periods of time.

5. Sensitivity reactions

- This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:

- Before you start taking your pills.
- Anytime you are unsure what to do.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.

- If you miss pills you could get pregnant. This includes starting the pack late.
- The choice is yours: either you are late or you are not late.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn’t go away, check with your doctor or clinic.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up those missed pills.

- On the day you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason: IF YOU TAKE SOME MECHANIC, including some antibiotics, your pills may not work as well. Use a back-up method (such as condoms, foam or sponge) until you check with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic about how to make pill-taking easier for you.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNCERTAIN ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS:

- DETERMINE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it about the same time every day.

- LOOK AT YOUR PILL PACK TO SEE THAT IT HAS 28 PILLS.

- The 28 pill package has 21 “active” pills (with hormones) to take for 3 weeks. This is followed by 1 week of light green “reminder” pills.

ALYACEN 7/7/7:

There are 7 white to off-white “active” pills, 7 light peach “active” pills, 7 peach “active” pills and 7 light green “reminder” pills.

3. ALSO FIND:

1. when on the pack to start taking pills,
2. where on the pack to start taking pills,
3. see pill package diagram above.

4. BEFORE YOU TAKE YOUR PILL AT ALL TIMES:

- ANOTHER KIND OF BIRTH CONTROL, (such as condoms, foam or sponge) use as a back-up in case you miss pills.

 AN EXTRA, FULL PILL PACK.

5. WHEN TO START THE FIRST PACK OF PILLS

- You have a choice of starting with your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

SUNDAY START:

ALYACEN 7/7/7:

- Take the first white to off-white “active” pill of the first pack on the Sunday after your period starts, even if you are still bleed. If your period begins during Sunday, start the pack the same day.

- (see another method of birth control as a back-up method if you have any unsure from the Sunday you start your first pack until the next Sunday (7 days).

DAY 1 START:

ALYACEN 7/7/7:

- Take the first white to off-white “active” pill of the first pack during the first 24 hours of your period.

1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).

2. Place this day label strip on the tablet blister card over the area that has the days of the week (starting with Sunday) imprinted in the plastic.

Peel and place label here.

Note: If the first day of your period is a Sunday, you can skip step #1 and #2.

You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.

- Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).

- Do not skip pills even if you do not have sex very often.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:

- Start the next pack on the day after your last light green “reminder” pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

ALYACEN 7/7/7:

If you MISS 1 white to off-white, light peach, or peach “active” pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.

2. You do not need to use a back-up birth control method if you have sex.

ALYACEN 7/7/7:

If you MISS 2 white to off-white or light peach “active” pills in a row in WEEK 1 OR WEEK 2 of your pack:

1. Take 2 pills on the day you remember and 2 pills the next day.

2. Then take 1 pill a day until you finish the pack.

3. YOU MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. YOU MUST use another birth control method (such as condoms, foam or sponge) as a back-up for these 7 days. If you MISS 2 peach “active” pills in a row in the 3RD WEEK:

1. If you are a Sunday Starter:

- Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

2. If you are a Day 1 Starter:

- THROW OUT the rest of the pill pack and start a new pack that same day.

3. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.

4. YOU MUST BECOME PREGNANT if you have sex in the 7 days after you miss pills. YOU MUST use another birth control method (such as condoms, foam or sponge) as a back-up method for those 7 days.

A REMINDER FOR THOSE ON 28-DAY PACKS:

1. TAKE any of the light green “reminder” pills in Week 4. THROW AWAY the pills you missed. Keep taking 1 pill each day until the pack is empty. You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

Use a back-up method (such as condoms, foam or sponge) until you check with your doctor or clinic.

PREGNANCY DUE TO PILLS FAILURE

Contraceptive Oral Contraceptives

The incidence of pill failure (failure in preventing pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year) if taken every day as directed. Set failure rates are about 3%. If failure does occur, the risk to the fetus is minimal.

PREGNANCY AFTER STOPPING THE PILL

There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you start oral contraceptives. It may be advisable to postpone conception until you begin menstruating regularly once you have stopped taking the pill and become pregnant.

OVERDOSAGE

Serious or infrequent have not been reported. Ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea and vomiting. In extreme cases, contact your health care provider or pharmacist.

OTHER INFORMATION

Your health care provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the health care provider believes that it is a good medical practice to postpone it. You should be examined at least once a year. Be sure to inform your health care provider if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your health care provider, because this is a time to determine if there are early signs of side effects of oral contraceptive use.

Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others or who may want birth control pills.

HEALTH BENEFITS FROM ORAL CONTRACEPTIVES

In addition to preventing pregnancy, use of combination oral contraceptives may provide certain benefits. They are:

- Menstrual cycles may become more regular.
- Bleeding or spotting during the pill may be less.
- Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to deficiency is less likely to occur.
- Acne or other symptoms during menstruation may be encountered less frequently.
- Nausea or vomiting or loss of appetite may occur less frequently.
- Severe pelvic inflammatory disease may occur less frequently.
- Oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the uterine lining.

If you want more information about birth control pills, ask your doctor/health care provider or pharmacist. They have a more technical leaflet called the Professional Labeling, which you may wish to read. The professional labeling is also published in a book entitled Physicians’ Desk Reference, available in many book stores and public libraries.

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