

# **Abortion**

## **Making A Decision**

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Commonwealth of Pennsylvania

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*A Child is Born*  
Dell Publishing Co.

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# INTRODUCTION

The information in this booklet has been developed to give a woman basic information before making a decision about having an abortion.

It illustrates and describes, at two week intervals, how and unborn child grows during the stages of a woman's pregnancy. Also provided is information about the chances of a baby's survival when born at a given gestational age. Survival here is defined as living 28 days after birth.

Information is given about abortion methods and the medical risks and emotional reactions of abortion. Also described are the medical risks of childbirth. However, it should be emphasized that as technology and medical advances occur, the medical risks associated with abortion and childbirth are diminishing.

State health care programs that pay or help pay for medical bills for prenatal care, childbirth and neonatal care are explained in this publication. A directory of names, addresses and telephone numbers of County Assistance Offices and social service agencies is also available. The directory is broken down by county, so caller can get information and help from places located close to where they live.

By calling or visiting the agencies and offices, a woman can find out about alternatives to abortion, adoption and the kinds of assistance available to help her through pregnancy and childbirth and while she is raising her child.

Furthermore, every woman should know that:

- It is unlawful for any individual to coerce a woman to undergo an abortion.
- Any physician who performs an abortion upon a woman without obtaining her informed consent or without according her a private medical consultation may be liable to her for damages in a civil action at law.
- The father of a child is liable to assist in the support of that child, even in instances where the father has offered to pay for an abortion.
- The law permits adoptive parents to pay costs of prenatal care, childbirth and neonatal care.

## DEVELOPMENT OF AN UNBORN CHILD

The age of an unborn child (gestational age) is measured in two different ways. Embryologists (doctors and scientists who study the early stages of pregnancy) measure the age of an unborn child from the estimated day of conception (the time when you actually become pregnant). This book refers to that measurement of gestational age a "weeks fertilization".

On the other hand, practicing doctors measure an unborn child's age from the first day of your last menstrual period which usually occurs two weeks before fertilization (conception). This book refers to that measurement as "weeks menstrual".

On the following pages are pictures and descriptions of how an embryo and fetus grow in a woman's body.

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The dimensions (inches/millimeters and pounds/grams) are based on information presented by *Williams Obstetrics*, Eighteenth Edition, 1989.

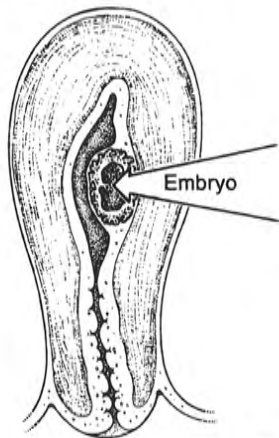
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# DESCRIPTION OF GROWTH WITH PICTURES

After fertilization, the egg divides and multiplies to form the embryo.

## 2 Weeks Fertilization 4 Weeks Menstrual

The developing embryo is about the size of a pinhead and is now inside a protective shell of special cells in the uterus wall. The cells are beginning to grow into groups that will be parts of the embryo



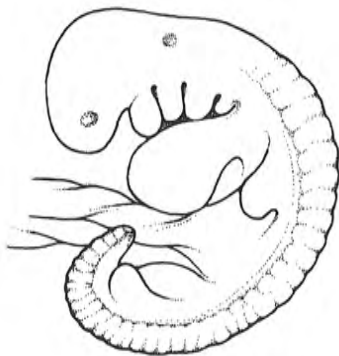
## 3 Weeks Fertilization 5 Weeks Menstrual

The embryo and first nerve cells have formed.



## 4 Weeks Fertilization

The embryo is about  $\frac{1}{4}$  inch long (5 millimeters). A blood vessel forms which will later develop into the heart and circulatory system. It begins to pump blood. At about the same time, a ridge of tissue forms down the length of the embryo. That tissue will later develop into the brain and spinal cord. Arm and leg buds are present.



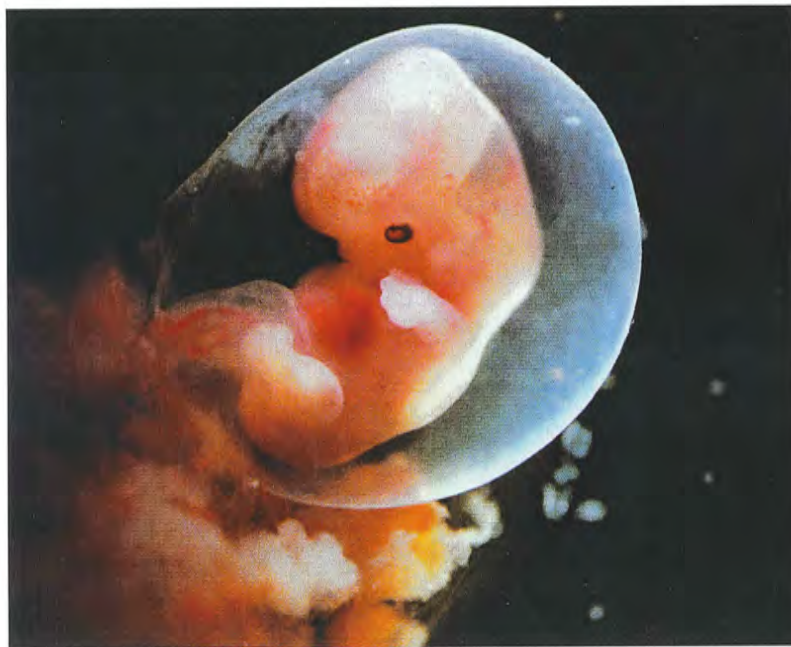
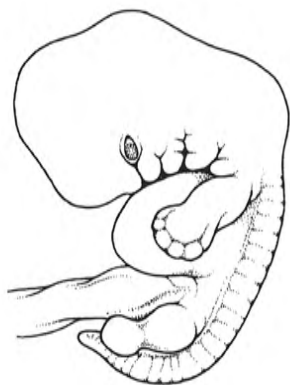
## 6 Weeks Menstrual





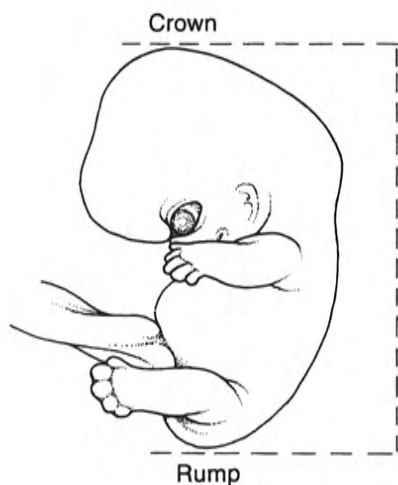
## 6 Weeks Fertilization

This embryo is about  $\frac{3}{4}$  inch long (23 millimeters). Cells of the embryo continue to multiply and start to form the brain. At the other end is a tail bud which will become the end of the spine. Fingers and toes are starting to appear. Cells which also are multiplying in other parts of the embryo are starting to form the eyes, jaws, lungs, stomach, intestines and liver.



## 8 Weeks Fertilization

This embryo is called a fetus. The length of the fetus, measured from the top of the head to the bottom trunk (crown to rump), is about  $1\frac{1}{2}$  inches (40 millimeters). The head is large. Structures which will form the eyes, ears, arms and legs are identifiable. Muscles and skeleton are developing.



## 10 Weeks Fertilization

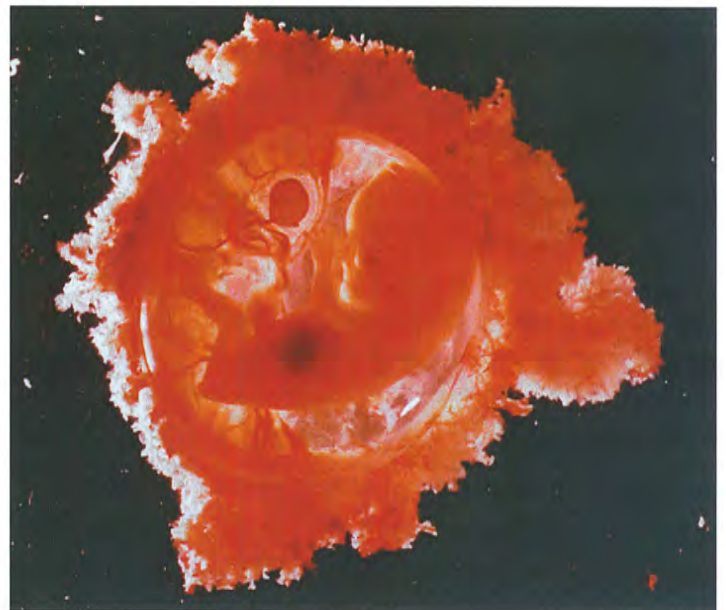
All major external body features have appeared. The fetus crown to rump is approximately 2½ inches long (60 millimeters), and weigh roughly ½ ounce (14 grams). The muscles continue to develop. Fingers and toes are distinct and have nails.



## 12 Weeks Menstrual

## 12 Weeks Fertilization

The fetus measures approximately 3½ inches long (87 millimeters), and weighs roughly 1½ ounces (45 grams). The head is still the dominant part of the fetus. The eyes are beginning to grow toward the front of the head and 20 buds are present for baby teeth. There are eyelids and the nose is developing a bridge. External genitals have been developing so that the sex can be identified.





## 14 Weeks Fertilization

## 16 Weeks Menstrual

The length of the fetus is approximately 5 inches (120 millimeters), crown to rump, and the weight is roughly 4 ounces (110 grams). Limbs are well developed. The skin appears transparent. The head is large compared to other body structures.



## 16 Weeks Fertilization

## 18 Weeks Menstrual

The fetus from crown to rump is now roughly 5½ inches long (140 millimeters). Weight is almost 8 ounces (200 grams). Skin is pink and transparent.

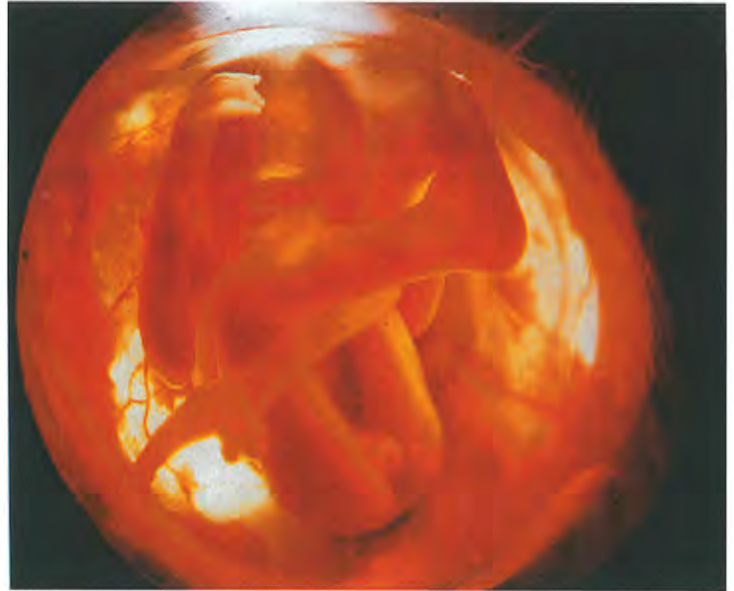




## 18 Weeks Fertilization

## 20 Weeks Menstrual

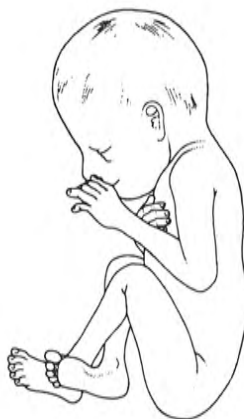
Crown to rump length is about 6¼ inches (160 millimeters). Weight is almost ¾ pound (320 grams). Fine, downy hair as well as scalp hair appears on the fetus. Respiratory movements occur, but the lungs have not developed enough to permit survival outside the uterus. By this time the woman can feel the fetus moving.



## 20 Weeks Fertilization

## 22 Weeks Menstrual

Crown to rump length is about 7½ inches (190 millimeters). Weight is about one pound (460 grams). The kidneys are starting to work and the air sacs of the lungs are starting to develop. The fetus is more active turning from side to side. Up to this time, there is very little chance that a baby would survive outside the uterus. Selected Pennsylvania hospitals report that 0-10% of babies treated in the neonatal intensive care units of those hospitals report that 0-10% of babies treated in the neonatal intensive care units of those hospitals survived for at least 28 days or to the day when they were discharged from those intensive care units.\*



*\*There are, however, no definitive published studies on survival rates for babies born at this age.*

## 22 Weeks Fertilization

Crown to rump length is about 8¼ inches (210 millimeters) and weight has increased to about 1¼ pounds (630 grams). Head and body hair are evident. The skin is wrinkled and still extremely thin. Eyebrows and eyelashes are more evident. Fat is beginning to form on the fetus and usually, evidence of the fetal skeleton can be detected. At this time, changes are occurring in lung development so that some babies at this stage may be able to survive outside the uterus, given the technology and intensive care services provided in many hospitals. Still, chances of survival are poor. Selected Pennsylvania hospitals report that for babies born at this time and treated in the neonatal intensive care units of those hospitals, up to 66% survived for at least 28 days or to the day when they were discharged from the neonatal intensive care unit.\* If the baby lives, there is a likelihood it will have long term disabilities.



## 24 Weeks Fertilization

Crown to rump length is about 9 inches (230 millimeters) and the average weight is two pounds (820 grams). Lungs continue to develop. Body movements are stronger. Skin is red and wrinkled and covered with fine soft hair. Selected Pennsylvania hospitals report that for babies born at this time and treated in the neonatal intensive care unit of those hospitals, up to 82% survived for at least 28 days or to the day when they were discharged from the neonatal intensive care unit.\*



## 26 Weeks Menstrual

Photo not available

\*There are, however, no definitive published studies on survival rates for babies born at this age.



## 26 Weeks Fertilization

Crown to rump length is about 10 inches (250 millimeters). Weight is about 2½ pounds (1,000 grams). The fetus continues to develop and grow. Eyes are partially open. According to national statistics, about 90% of babies born at 28 through 29 weeks menstrual survive.



Photo not available

## 28 Weeks Fertilization

Crown to rump length is about 10½ inches (270 millimeters) and weighs 1,300 grams or almost 3 pounds. Fat is accumulating and the body is more rounded. Fetus can open and close its eyes, suck its thumbs and cry. National statistics show that about 96% of babies born at 30 through 31 weeks menstrual survive.



## 30 Weeks Menstrual



## 30 Weeks Fertilization

Crown to rump length is about 11 inches (280 millimeters). Weight is more than 3 pounds (1,700 grams). The fetus continues to develop with wrinkles appearing on the soles of the feet. About 98% of babies born at 32 through 33 weeks menstrual survive (based on national statistics).



Photo not available

## 32 Weeks Fertilization

Crown to rump length is about 12 inches (300 millimeters). Weight is about 4½ pounds (2,100 grams). Skin is pink and smooth. Fat continues to accumulate, and the fetus continues to gain weight steadily. About 99% of babies born at 34 through 35 weeks menstrual survive (based on national statistics).



## 34 Weeks Menstrual





## 34 Weeks Fertilization

Crown to rump length is about 12½ inches (320 millimeters). Weight is about 5½ pounds (2,500 grams). The fetus is more round and plump and is almost fully developed. The face is less wrinkled. More than 99% of babies born at 36 through 37 weeks menstrual survive (based on national statistics).



Photo not available

## 36 Weeks Fertilization

Crown to rump length is about 13½ inches (340 millimeters). Weight is about 6½ pounds (2,900 grams). At this time, in most cases, the fetus is fully developed. More than 99% of babies born at 38 through 39 weeks menstrual survive (based on national statistics).



## 38 Weeks Menstrual



# ABORTION METHODS AND MEDICAL RISKS

There are three ways a pregnancy can end: a woman can give birth, a woman can have a miscarriage or she can elect to have an abortion. If you make an informed decision to have an abortion, you and your doctor will need to consider how long you have been pregnant before deciding which abortion method to use. Based on data from the Centers for Disease Control and Prevention (CDC), the risk of dying as a direct result of a legally induced abortion is less than one per 100,000.

## **The First Trimester**

Doctors use a vacuum aspiration method during the first trimester (the first three months of pregnancy). The doctor must first check the size of your uterus. Your doctor will ask you to lie on your back and bend your knees. He or she will place one hand in your vagina and the other on your abdomen (belly). The doctor will look at the opening of your uterus (the cervix) using a speculum (a special instrument). Next, the doctor will spray or inject medicine on your cervix. This prevents you from feeling any pain. Then the doctor will put a catheter (a soft, clear tube similar to a long straw) into your cervix. The catheter is connected to a machine that acts like a vacuum cleaner. The fetus is sucked out of the womb through the catheter.

If more than six weeks have passed since your last normal period, the doctor must first gently open (dilate) the cervix. He or she will use a larger, firmer plastic tube (a curette) to remove (evacuate) the fetus.

Ending a pregnancy in the first trimester is considered minor surgery. However, in one out of every one hundred abortions, the uterus may not be completely emptied or it may become infected. Both problems are treatable. Also, in one out of every 500 abortions the catheter may go through the wall of the uterus by accident. If this happens, the woman would need surgery to fix the tear.

## **The Second Trimester**

Usually during a second trimester (fourth, fifth, and sixth months of pregnancy), to perform an abortion, the doctor opens (dilates) the cervix and empties (evacuates) the uterus. This method is known as dilation and evacuation (D & E).

When this abortion method is used in the second trimester, the doctor may insert a sponge-like material into the cervix. As the sponge gets wet it becomes larger, opening the mouth of the cervix. The doctor will remove the sponge two to sixteen hours later. The doctor uses forceps to remove the fetus or fetal parts; the doctor may also suction the fetus or fetal parts by vacuum aspiration using a larger catheter than described for the first trimester. The afterbirth is most commonly removed by vacuum aspiration.

Before the doctor will perform this procedure, he or she needs to feel the size of the uterus to determine the gestational age of the fetus. If the age is determined to be late in the second trimester, the doctor may elect to perform the abortion by labor induction.

During labor induction, labor can be started (induced) by injecting medicines or salt water into the fetal bag of waters (amniotic sac). The medicine can be injected into the bag of waters by cleaning the belly (abdomen) to kill germs on the skin; putting numbing medicine (anesthetic) into the skin; and pushing a needle through the skin into the bag of waters. Medicine may also be injected into the woman's bloodstream through her vein to induce labor. Labor will usually begin in two to four hours.

Generally, labor induction requires a longer stay and is not performed in a clinic setting. If the afterbirth is not removed with the fetus during labor induction, the doctor must open the cervix and suction the uterus as described in the vacuum aspiration method.

When an abortion is performed by the D & E method, there is virtually no chance that the fetus will live through the procedure. When an abortion is performed late in the second trimester, the doctor may elect to inject medicine into the fetus to terminate it before doing the vacuum aspiration. If the labor induction method is used, there is a minimal chance that a baby could live for a short period of time. The chance of living outside the uterus increases as gestational age increases. In the event the baby removed is alive, any physician or other medical personnel attending the baby is required by law to provide the type and degree of care and treatment which in the good faith judgment of the physician is commonly provided to any other person under similar conditions and circumstances.

Complications involved in second trimester abortions from D & C are the same as in the first trimester: the uterus may not be completely emptied, an infection may occur or instruments may tear a hole in the uterus. In second trimester abortions, there may also be heavy bleeding for a few days after the pregnancy has ended. These problems do not happen often and can be medically treated.

Complications in abortions are less frequent in the first eight weeks of pregnancy than later. Labor induction abortion carries the highest risk for problems.

Women who end their pregnancies by vacuum aspiration, labor inductions or D & E, do not usually have problems getting pregnant later in life. However, it is possible that having many abortions may make it difficult to have children.

Remember, every method used to end a pregnancy may cause problems. Ask your doctor about all possible problems so he or she can provide you with advice.

### **The Third Trimester**

Your physician may advise you to end your pregnancy early, between 24 and 38 weeks gestation (weeks menstrual). Should this advice call for the use of any means to end your pregnancy with knowledge that the termination by those means will, with reasonable likelihood, cause the death of the unborn child, then the termination of pregnancy using such means is an abortion. An abortion at this stage of your pregnancy may only be done if your physician reasonably believes that it is necessary to prevent either your death or a substantial and irreversible impairment of one of your major bodily functions.

When a pregnancy is ended at this stage, one of two procedures is performed: labor induction or cesarean section.

If pregnancy is ended by labor induction during the third trimester, it is quite different from the description above. In the third trimester, labor can be started by injection medicine directly into the bloodstream (vein) of the pregnant woman. Labor and delivery of the fetus during the third trimester are similar to childbirth. The duration of the labor depends on the size of the baby and the "readiness" of the womb.

As with childbirth, the complications of labor induction during the third trimester include: infection, heavy bleeding, stroke and high blood pressure. When medicines are used to start labor, there is a greater risk of rupture of the womb than during normal childbirth.

If labor cannot be started by injection medicine into the pregnant woman, or if the pregnant woman is too sick to undergo labor, a cesarean section may be done. A cesarean section is surgery to remove the baby from the womb. Generally, the woman is made numb and sleepy and/or by a combination of medicines injected into the vein or spine and/or medicine inhaled into the lungs. Then the belly is prepared by washing with soapy solution (antiseptic) to kill germs. The belly and womb are then surgically cut open and the baby removed.

The complications seen with cesarean section are similar to those seen with childbirth and with administration of anesthesia: sepsis (severe infection); emboli (blood clots to the heart and brain); aspiration pneumonia (stomach contents breathed into the lungs); hemorrhage (severe bleeding); and injury to the urinary tract.



The likelihood that your baby will live after it is delivered during this stage of your pregnancy depends on the baby's gestational age and health at the time of delivery. When an abortion is performed during the third trimester, the following steps must be taken:

- (1) The physician who terminates the pregnancy must certify in writing that based upon the physician's medical examination and medical judgment, the abortion is necessary to prevent either your death or substantial and irreversible impairment of one of your major bodily functions.
- (2) A second physician must also examine you and certify in writing that based upon that physician's medical examination and medical judgment, the abortion is necessary to prevent either your death or substantial and irreversible impairment of one of your major bodily functions.
- (3) The abortion must take place in a hospital.
- (4) The physician must select a procedure that is most likely to allow the unborn baby to live.
- (5) A second physician must also be present in the room in which the abortion is performed. That physician will take charge of medical care for the baby immediately after it is delivered and must take all reasonable steps necessary to preserve the baby's life and health.

The physician is not required to use the abortion method that would provide the best opportunity for the baby to live if the physician determines in his or her good faith medical judgment that use of that method poses a significant greater risk to your life or to the substantial and irreversible impairment of one of your major bodily functions than would another method.

In the case of a medical emergency, a physician is also not required to comply with any condition listed above which, in the physician's medical judgment, he or she is prevented from satisfying because of the medical emergency.

## EMOTIONAL REACTIONS

Because every person is different, one woman's emotional reaction to an abortion may be different from another's. After an abortion, a woman may have both positive and negative feelings, even at the same time. One woman may feel relief, both that the procedure is over and that she is no longer pregnant.

Another woman may feel sad that she was in a position where all of her choices were hard ones. She may feel sad about ending the pregnancy. For awhile after the abortion she also may feel a sense of emptiness or guilt, wondering whether her decision was right. Some women who describe these feelings find they go away with time. Other women find them more difficult to overcome.

Certain factors can increase the chance that a woman may have a difficult adjustment to an abortion. One of these is not having any counseling before consenting to an abortion. When help and support from family and friends are not available, a woman's adjustment to the decision may be more of a problem.

Other reasons why a woman's long term response to an abortion can be poor may be related to past events in her life. For example, negative feelings could last longer if she has not had much practice making major life decisions or already has serious emotional problems.

Talking with a professional and objective counselor can help a woman fully consider her decision before she takes any action.



# MEDICAL RISKS OF CHILDBIRTH

Continuing a pregnancy and delivering a baby is usually a safe, healthy process. Based on data from the Centers for Disease Control and Prevention (CDC), the risk of dying as a direct result of pregnancy and childbirth is less than 10 in 100,000 live births. The risk is higher for Blacks (22.0 in 100,000).

The most common causes of death of a pregnant woman are:

- Emboli (blood clots affecting the heart and brain).
- Eclampsia (high blood pressure complications affecting pregnancy)
- Hemorrhage (severe bleeding)
- Sepsis (severe infection).
- Cerebral vascular accidents (stroke, bleeding in the brain).
- Anesthesia-related deaths.

Together, these causes account for 80% of all deaths relating to a woman's pregnancy. Unknown or uncommon causes account for the remaining 20% of deaths relating to pregnancy. Women who have chronic severe diseases are at greater risk of death than healthy women.

Continuing your pregnancy also includes a risk of experiencing complications that are not always life threatening.

- Approximately 15 to 20 of every 100 pregnant women require cesarean delivery (delivery by cutting open the abdomen).
- One in 10 women may develop infection during or after delivery.
- Approximately one in 20 pregnant women have blood pressure problems.
- One in 20 women suffer from excessive blood loss at delivery.

## INFORMATION ABOUT STATE HEALTH CARE PROGRAMS THAT PAY FOR PRENATAL CARE, CHILDBIRTH AND NEONATAL CARE

You may or may not qualify for financial help for prenatal, childbirth and neonatal care, depending on your income. If you qualify for financial help for prenatal, childbirth and neonatal care, depending on your income. If you qualify, programs such as the state's Medical Assistance program called Healthy Beginnings, will pay or help for or help pay the cost of doctor, clinic, hospital and other related medical expenses to help you with prenatal care, childbirth delivery services and care for your newborn baby.

Under Healthy Beginnings, a pregnant woman is allowed to have more income to qualify than the income set under the regular Medical Assistance program. You can apply for this financial help at your local County Assistance office. Your County Assistance Office also can tell you which providers participate in Healthy Beginnings and can answer your questions about other available benefits.

Brochures explaining Healthy Beginnings are available. Call the Welfare Help Line at 800-692-7462 for information about eligibility.

# DIRECTORY

The decision to have an abortion or have a baby must be carefully considered. If you need more help or guidance, a directory is available of county and social service agencies and organizations. You are encouraged to contact them if you need more information so you can make an informed decision. If you want to see the directory, please ask your doctor, nurse or counselor to provide you with it. Or, if you want to obtain a copy of the directory, call the toll free State Health Line at 1-877-724-3258.

## **Health Notice**

### **November 13, 2000**

The Federal Food and Drug Administration (FDA) has approved mifepristone (trade name Mifeprex) for the termination of early pregnancy, defined as 49 days or less, counting from the beginning of the woman's last menstrual period. The drug will be available for use in the very near future. The attached materials provide important information regarding the Federal Drug Administration's approval of mifepristone for the termination of early pregnancy.

In Pennsylvania, the administration of mifepristone for the purpose of inducing an abortion is regulated under the Abortion Control Act. The Department interprets the Abortion Control Act to require that the giving of mifepristone or the giving or prescribing of any other drug to a woman to induce an abortion take place only in a facility registered with the Department to perform abortions. At present, pursuant to the FDA approval, mifepristone will not be available at pharmacies and will be provided to only those physicians who satisfy criteria imposed by the FDA.

The Abortion Control Act requires the Department to publish printed materials that contain objective information describing common abortion procedures, the medical risks associated with abortion procedures and carrying a child to term, and the possible detrimental psychological effects of abortion. Except in a medical emergency, at least 24 hours in advance of an abortion a physician who either refers a woman for an abortion or performs the abortion, or either's designated agent as authorized by the Abortion Control Act, is to apprise a woman considering an abortion of the availability of these materials. The materials are to be provided to the woman if she requests them. Compliance with these requirements is necessary to secure the woman's informed consent to an abortion.

The attached medication guide and question and answer sheets relating to mifepristone were prepared by the FDA. They are to be included with the other materials prepared by the Department that are to be made available to a woman before she makes a decision to undergo an abortion. These materials should be used unless/until the Department and/or the FDA provides new or revised information.

These materials explain what mifepristone is and how it works on a woman's body, possible side effects, the medical treatment protocol for giving mifepristone to a woman to terminate an early pregnancy, medical circumstances under which a woman should not take mifepristone, and other information that will help a woman make a decision regarding whether or not to undergo an abortion by taking this drug.

In addition to the attached documents, other materials developed by the FDA, which are pertinent to the use of mifepristone to induce abortions, may be accessed at: <http://www.fda.gov/cder/drug/infopage/mifepristone>.

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## Mifepristone Questions and Answers

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### **1. What is MIFEPREX (mifepristone) and how does it work?**

Mifepristone is a drug that blocks a hormone called progesterone that is needed for pregnancy to continue. Mifepristone, when used together with another medicine called misoprostol, is used to end an early pregnancy (49 days or less since your last menstrual period began).

### **2. Is mifepristone approved in any other countries?**

Yes, mifepristone has also been approved in the United Kingdom, Sweden, and other countries.

### **3. Who should not take mifepristone?**

Some women should not take mifepristone. Do not take mifepristone if it has been more than 49 days since your last menstrual period or if you have:

- a tubal pregnancy
- an intrauterine device (IUD) in place (it must be removed before you take mifepristone)
- problems with your adrenal glands (the glands near your kidneys)
- been treated with certain steroid medications for a long period of time
- bleeding problems or are taking anticoagulant (blood thinning) drug products
- had an allergic reaction to mifepristone, misoprostol, or similar drugs

It is important that you understand the need for two follow-up visits with your health care provider and that you have access to a medical care facility in case of an emergency.

Mifepristone has not been studied in women who are heavy smokers. Please tell your doctor if you smoke more than 10 cigarettes a day.

### **4. Is mifepristone distribution restricted?**

Yes, mifepristone is supplied directly to doctors who meet certain qualifications. It is not and will not be available in pharmacies, and it is not legally available over the Internet.

### **5. Why are there restrictions for this drug?**

Studies of mifepristone were conducted by doctors who had certain qualifications. Both the drug sponsor and the 1996 Reproductive Drug Products Advisory Committee also recommended that FDA restrict distribution of mifepristone to qualified doctors. FDA has concluded that these restrictions are necessary for the safe use of the drug.



## **6. What qualifications must doctors have to obtain mifepristone?**

Doctors must have the ability to date pregnancies accurately and to diagnose tubal pregnancies. Doctors must also be qualified to provide any necessary surgery, or have made arrangements for any necessary surgery. Doctors must ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, such as dispensing the Medication Guide and reporting any adverse events to the sponsor.

## **7. What authority does FDA have to restrict distribution of a drug?**

The law authorizes FDA to approve new drugs only if they have been demonstrated to be safe and effective for use under the conditions of use recommended in the label. FDA has broad authority to require restrictions on distribution to ensure safe and effective use. FDA's full legal authority to restrict distribution of a drug is described in more detail in the preamble to agency drug regulations. Federal Register Notice.

## **8. Can health care providers other than doctors dispense mifepristone?**

Some states allow physicians to supervise other health care practitioners, such as certified registered nurse practitioners and nurse midwives, and these states may allow a supervised health care provider to dispense mifepristone. Health care providers should check their state law provisions.

## **9. Is there an age restriction for termination of pregnancy?**

State law determines whether there are any restrictions on minors obtaining surgical or medical abortions. FDA has not set any separate age restriction on the provision of Mifepristone states may set age restrictions on termination of pregnancy if they believe such restrictions are appropriate.

## **10. Are there studies with mifepristone in women under the age of 18?**

Studies to evaluate mifepristone included women ages 18-45.

## **11. What are the possible side effects of using mifepristone?**

Mifepristone treatment will cause vaginal bleeding. In some cases vaginal bleeding can be very heavy. In a few cases, this bleeding will need to be stopped by a surgical procedure.

Other possible side effects of the treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.

The possible side effects are described in the Medication Guide. Please read the Medication Guide.

## **12. What is a Medication Guide?**

A Medication Guide is a leaflet that contains certain FDA-approved information, written especially for patients.

## **13. Why did FDA develop a Medication Guide for mifepristone?**

FDA determined that a Medication Guide was necessary for women to be able to use mifepristone effectively and safely. It is important for women to be fully informed about how mifepristone works and about its risks, as well as the need for follow-up visits with their health care provider, especially on the 14<sup>th</sup> day after mifepristone is administered. The Medication Guide will help ensure that women follow the directions for use and that they return to their health care provider for follow-up visits.

Before you receive mifepristone, your doctor will provide you with the Medication Guide and ask you to sign a statement (Patient Agreement) that you have decided to end your pregnancy.

## **14. Can I become pregnant again if I take mifepristone?**

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using a birth control method of your choice as soon as your pregnancy ends.

## **15. Does FDA endorse the use of this drug?**

FDA does not endorse or promote any drug product. The agency evaluates all drug applications submitted by sponsors to determine whether a drug is safe and effective for its proposed indication under the conditions of use in the labeling. This means that the benefits of the drug outweigh its risks. The same standards were applied to the new drug application for mifepristone as are applied to all applications.

## **16. How much will mifepristone cost?**

Manufacturers establish prices for prescription drugs. FDA has no input into or jurisdiction over drug pricing. FDA does not know what mifepristone will cost when it becomes available.

## **17. Will insurance companies pay for mifepristone?**

The FDA has no input into or legal control over whether an insurance company does or does not cover the cost of a drug. Insurance coverage is a decision made by your insurance provider. Please call your insurance company if you have questions about whether your particular insurance provider will cover the cost of mifepristone.

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## Mifepristone Medication Guide

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### Mifeprex (MIF-eh-prex) (mifepristone)

Read this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your health care provider (provider).

#### **What is the most important information I should know about Mifeprex?**

**Mifeprex is used to end an early pregnancy.** It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (7 weeks) or less since your last menstrual period began. By using Mifeprex, you probably will not need a surgical procedure to end your pregnancy.

**When you use Mifeprex, you also need to take another medicine called misoprostol.** You take misoprostol two days after you take Mifeprex.

**You need to sign a statement (PATIENT AGREEMENT).** Before you get Mifeprex, you will need to read and understand the information in this Medication Guide. Then you will need to sign a statement that you have decided to end your pregnancy.

**You must visit your provider on Day 1, Day 3, and about Day 14.** See the section called “How should I take Mifeprex?” for information about what happens at each visit. If you do not follow all the steps in “How should I take Mifeprex?” you will not know if your pregnancy has ended.

**What to do if you are still pregnant after Mifeprex or Mifeprex with misoprostol treatment.** If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

**Symptoms to expect.** This treatment causes cramping and bleeding. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must return to your provider on Day 3 and about Day 14.

If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol. This is a medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9-16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue that come from your uterus. This is an expected part of ending the pregnancy.

**Heavy bleeding and the need for surgery.** In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (curettage) to stop it. This is why you must talk with your provider about what to do if you need emergency care to stop heavy and possibly dangerous bleeding.

**Before you take Mifeprex.** Your provider will give you a telephone number to call if you have any questions, concerns, or problems. Your provider will also give you the name and phone number of who will handle emergencies.

**Talk with your provider.** You and your provider should discuss the benefits and risks for you of using Mifeprex.

## **What is Mifeprex?**

Mifeprex blocks a hormone needed for your pregnancy to continue. When used together with another medicine called misoprostol, Mifeprex ends your pregnancy. About 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

## **Who should not take Mifeprex?**

Some women should not take Mifeprex. Do not take it if:

- It has been more than 49 days (7 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your provider has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next two visits.
- You cannot easily get emergency medical help in the two weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Tell your provider about all your medical conditions to find out if you can take Mifeprex. Also, tell your provider if you smoke at least 10 cigarettes a day.

## **How should I take Mifeprex?**

- **Day 1 at your provider's office:**
  - Read this Medication Guide.
  - Discuss the benefits and risks of using Mifeprex to end your pregnancy.
  - If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
  - After getting a physical exam, swallow three tablets of Mifeprex.



- **Day 3 at your provider's office:**
  - Your provider will check to see if you are still pregnant.
- If you are still pregnant, take two misoprostol tablets.
- Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your health care provider may send you home with medicines for these symptoms.
- **About Day 14 at your provider's office:**
  - This follow-up visit is very important. You must return to the provider about two weeks after you took Mifeprex to be sure you are well and that you are not pregnant.
  - Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

### **What should I avoid while taking Mifeprex and misoprostol?**

You should not take certain other medicines, because they may interfere with the treatment. Ask your provider about what medicines you can take for pain. Do not take any other prescriptions or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your provider about them.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your provider if you should stop using your breast milk for a few days.

### **What are the possible side effects of using Mifeprex?**

See the section "What is the most important information I should know about Mifeprex?" for symptoms to expect.

In some cases, bleeding can be very heavy. In a very few cases, this bleeding will need to be stopped by a surgical procedure. Contact your provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding.

Other side effects of the treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. Your provider will tell you how to manage any pain or other side effects.

If you are worried about any side effects you have, talk with your provider about them. Your provider will give you a telephone number to call if you have any questions, concerns, or problems. Your provider's telephone number is \_\_\_\_\_.

## **When should I begin birth control?**

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

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Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. For more information, ask your provider for the information about Mifeprex that is written for health care professionals. Ask your provider if you have any questions.

This Medication Guide has been approved by the US Food and Drug Administration.

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*FDA/Center for Drug evaluation and Research*



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