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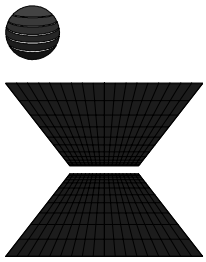
May 2001 "Drugs in Pregnancy & Lactation—Part II" 707-000-01-005-H01



THIS MONTH
"Drugs in Pregnancy & Lactation—II"

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MARK YOUR CALENDAR. 2001 QUIZ DEADLINE IS NOVEMBER 30, 2001.

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Recently we presented a lesson that discussed issues of concern when drugs are used during pregnancy and lactation. (***CE PRN***® Volume 22 Number 10; October 2000). The response to that topic was so overwhelming that we decided to revisit it. In the current lesson we review and expand upon the significant factors associated with drug use during pregnancy and lactation. The goal is to disseminate information regarding medications that may cause problems. This lesson provides 1.25 hours of credit (0.125 CEUs), and is intended for pharmacists in all practice settings.

The program ID # for this lesson is 707-000-01-005-H01.
Pharmacists completing this lesson by May 31, 2004 may receive full credit.
(May 31, 2003 for California.)

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

Upcoming topics for continuous participants: Common Diagnostic Procedures; Menopause; Drug-Food Interactions; Dosing for Pediatric Patients; Review of Alternative Therapies; New Oral Hypoglycemics.

If you have any comments, suggestions or questions, contact us at the above address, call 800-323-4305, or email us at info@wfprofessional.com. (In Alaska and Hawaii phone 847-945-8050).

The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the factors that influence diffusion of a drug through the placenta
.
2. Recognize the potential risk to the fetus from drugs ingested during pregnancy.
3. List the categories of drugs based on the potential benefits and risks during pregnancy.
4. Discuss some of the advantages associated with breast feeding.
5. Describe factors that influence excretion of drugs into the breast milk.

Since the 1950's, it has been assumed that during pregnancy the uterus and placenta act as barriers against adverse effects that may be caused to the fetus by foreign substances ingested by the expectant mother. However, the thalidomide disaster has shown that drugs and other substances can cross the placental barrier, causing serious damage. This drug, which was used as an anti-anxiety agent during the first trimester, had previously been declared to be safe in several species, and its teratogenicity was not suspected. Fetal exposure to thalidomide during critical periods of development has caused severe limb defects and other fetal malformations. Unfortunately, it took many years of use to realize the relationship between the drug and the resultant disasters.

The post-thalidomide era has witnessed an increased concern for the safety of using drugs during pregnancy and lactation. This concern led to federal drug regulation in 1962, which states that a drug must be safe and effective for its intended uses that are designated on the label. It is difficult to predict teratogenicity in humans from studies performed on animals. Teratology is the science that deals with structural (e.g., limbs, kidneys, heart) or functional (e.g., brain function, behavioral changes) fetal defects. A drug that may be proven safe in animals does not ensure safety in humans. For example, the initial safety data of thalidomide was based on animal studies. The reverse is true. A number of drugs that caused fetal malformation in animals failed to give the same results in humans. For example, corticosteroid compounds are teratogens in animals but not necessarily in humans. In spite of the fact that about 30 drugs have been proven to be significant teratogens to humans, the vast majority of drugs used in the USA carry a disclaimer statement in their package inserts and in published literature indicating that the safe use of this drug in pregnancy has not been established and should be used only if the anticipated benefits outweigh the potential risk to the fetus. Pharmaceutical manufacturers simply are reluctant to engage in efficacy and safety studies during pregnancy in light of the current ethical, regulatory and legal environment. Even though animal studies have provided a vast wealth of information concerning teratogenicity of drugs, the conclusions of these studies cannot be extrapolated from one species to another or from animals to humans. For example, thalidomide causes fetal malformation in humans and rabbits, but not in rodents. To help physicians in the decision-making process, in 1979 the FDA established the following five categories of drugs based on the potential benefits and risks for a pregnant woman and the fetus.

Category A: Indicates drugs for which well-controlled studies in pregnant women have failed to show a risk to the fetus. Even though one cannot entirely rule out a risk, it is assured that when a drug is placed in this category, its use during pregnancy is relatively safe.

Category B: Refers to drugs that show no evidence of risk to humans. Either animal studies failed to demonstrate a fetal risk in animals, but there are no adequate studies in humans; or animal studies have shown some fetal risk that have not been demonstrated in humans.

Category C: Also has two meanings. This category indicates that risk cannot be excluded. Either animal studies have shown fetal risk and no adequate studies in humans, or studies in humans and animals are lacking. However, potential benefits may outweigh the potential risk.

Category D: Applies to drugs that show positive evidence of risk in humans. Data indicates that drugs in this category show risk of birth defects in humans, but the potential benefits of the drugs may justify the potential risk. These drugs are usually used in life-threatening circumstances or in diseases for which safer drugs cannot be used, or are ineffective.

CE PRN® (ISSN 0199-5006) is owned and published by W-F Professional Associates, Inc.
400 Lake Cook Road, Suite 207, Deerfield, Illinois 60015.
William J. Feinberg, President
CE PRN® is published eleven times per year, monthly, January through November. Subscription rate is $85.00 per year. Second-Class Postage paid at Deerfield, Illinois 60015 and at additional mailing offices.

POSTMASTER: Send all address changes to
W-F Professional Associates, Inc., 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.
Mayl 2001

Category X: Applies to drugs that are contraindicated during pregnancy. Studies in both humans and animals have demonstrated fetal risk that clearly outweighs the potential benefits. The FDA advises that physicians should inform pregnant females of the potential risk to the fetus.

Suggestions have been made that the FDA should modify this classification to a more meaningful and evidence-based system.

HUMAN TERATOGENS

The following drugs are confirmed human teratogens.

Androgens: Masculinization of female fetus

Angiotensin-Converting Enzymes: Fetal or neonatal death

Busulfan, Chlorambucil, cyclophosphamide, mechlorethamine: Growth retardation, cleft palate, cardiac and other defects

Carbamazepine: Developmental delay

Cocaine: Microcephaly and neurobehavioral abnormalities

Coumarin derivatives: Fetal warfarin syndrome

Diethylstilbestrol: Vaginal adenosis and clear cell carcinoma in female offspring. In male offspring, hypogonadism and diminished spermatogenesis may occur.

Isotretinoin: Spontaneous abortion, micro/hydrocephaly, deformation of ear, face, heart and limbs.

Lithium: Increased risk of Ebstein anomaly (congenital condition of the heart symptoms of which are fatigue, palpitation, and dyspnea.)

Misoprostol: Limb reduction defects.

Penicillamine: Hyperflexibility of joints.

Phenytoin: Fetal hydantoin syndrome

Progestins: Masculinization of female fetus.

Smoking: Placental lesions, increased neonatal morbidity and mortality.

Streptomycin: Hearing impairment.

Tetracycline: Discoloration of deciduous teeth. Effects may be seen from four months of gestation on.

Thalidomide: Limb malformation, congenital heart defects and renal malformation.

Valproate: CNS and cardiac defects, facial changes.

Vitamin D: Large doses of Vitamin D may cause supervalvular aortic stenosis and elfin faces.

The mechanism of teratogenic agents is usually not known. The effects may become evident immediately after birth or may be delayed and appear later on in life. For example, exposure of female fetuses to the diethylstilbestrol may increase the risk of causing vaginal and/or cervical adenocarcinoma after puberty.

Drugs are transferred from the mother to the fetus through the placenta, which acts as a lipoprotein membrane. The driving force behind the diffusion of the drug through the placenta is the concentration gradient. Drugs having low molecular weight, lipid solubility, neutral polarity, and low protein binding properties, favor diffusion through the placenta. Most drugs have molecular weights that range from 250 to 400. Such drugs are capable of crossing the placenta without difficulty. However, compounds having molecular weight over 1000 do not cross the placenta passively. Warfarin, whose molecular weight is 1000, can cross the placenta causing fetal abnormalities, whereas heparin, which has a molecular weight of 20,000, cannot cross the placenta, and consequently will not cause any fetal malformation. Because of these characteristics, heparin is the recommended anticoagulant during pregnancy. Highly lipid soluble drugs, such as thiopental, can reach fetal circulation within a short period of time.

Studies indicate that about 86% of pregnant women take an average of about three medications (range 1 to 15) at some time during pregnancy. OTC drugs taken without medical advice were not included. These medications are usually taken to manage symptoms associated with pregnancy such as pain, nausea, vomiting and heartburn. Other drugs may be used to treat concurrent disease such as diabetes mellitus, asthma, rheumatoid arthritis, and hypertension.

A number of physical and physiologic changes take place during pregnancy that may change the pharmacokinetics of drugs and ultimately change the quantity of the drug reaching the fetus.

Pregnancy is usually accompanied by a delay in gastric emptying rate and a decreased GI motility. These changes result in slow but thorough absorption of the drug from the GI tract, and in turn, a lower

peak plasma concentration.

It appears that the decrease in plasma albumin of the pregnant woman, along with increased binding competition and decreased hepatic metabolism during the latter phases of pregnancy, may increase the amount of circulating free drug.

COMMON MEDICATION USED IN PREGNANCY

The primary medications used by women during pregnancy include antiemetics, antacids, analgesics, caffeine, nicotine and alcohol. As indicated earlier, medications to treat concurrent diseases may also be taken.

Antiemetics: Mild to severe nausea and vomiting occur in up to 90% of pregnant females. These symptoms take place mainly during the period from the third to seventh week of pregnancy, but usually cease by the end of the fourth month. The vast majority of women take antiemetics to relieve these symptoms. Although these symptoms are annoying, they do not pose harm, either to the fetus or to the pregnant woman. The exact mechanism that triggers nausea and vomiting is not clear. However, the increased plasma concentration of chorionic gonadotropin hormone and progesterone is believed to play a role in the etiology. Nonpharmacologic measures such as eating small, frequent meals that are high in carbohydrates or protein may reduce the intensity of nausea and vomiting. Avoidance of spicy food, noxious odors, and fatty food is recommended. If these measures fail to provide relief, then the use of drugs may be recommended.

Antiemetics such as meclizine, dimenhydrinate and certain phenothiazines may be used. Meclizine has been shown to be teratogenic in animals, but apparently not in humans. No evidence has been found to suggest a relationship between the use of dimenhydrinate and fetal malformation. The use of promethazine appears to have no adverse effects on the fetus. Prochlorperazine use has been linked to increased risk of cardiovascular abnormalities. Jaundice and extrapyramidal symptoms have occurred in neonates of mothers who have taken chlorpromazine during pregnancy. Even though meclizine and promethazine appear to have no fetal effects in humans, their use during the last weeks of pregnancy should be avoided.

Antacids: Antacids, that are primarily available as OTC drugs, are used by 30 to 50% of pregnant women to relieve symptoms of gastroesophageal reflux disorders. The use of aluminum, magnesium, and calcium salts is believed to be safe during the last two trimesters. Sodium bicarbonate should not be used, since it may lead to metabolic alkalosis. In high doses, magnesium trisilicate use may cause silicaceous nephroliasis, and thus it should be avoided.

Analgesics: Aspirin, as well as acetaminophen, are commonly used drugs for headache and pain relief. Although the use of aspirin for rheumatoid arthritis has diminished since the introduction of the NSAIDs, aspirin is frequently used during pregnancy. Aspirin was once believed to cause fetal malformations such as cleft palate and congenital heart disease. However, in subsequent and more comprehensive studies, aspirin has been shown to be safe. It is capable of crossing the placenta and causing birth defects in animals, but rarely in humans.

Acetaminophen is recommended for use during all stages of pregnancy. Its short-term use in therapeutic doses appears to be safe. Certain NSAIDs may cause constriction of the ductus arteriosus, when used during pregnancy.

Caffeine: Caffeine is a naturally occurring substance found in coffee, tea and cocoa. It is often included in OTC medications for the common cold, appetite suppression and CNS stimulation. It is also found in many soft drink beverages. Depending on the way it is brewed, 5 ounces of coffee may contain from 30 to 180 mg of caffeine. Stimulants usually contain from 100 to 200 mg of caffeine per tablet, whereas anorexics may contain up to 120 mg of caffeine per tablet. Because of its presence in popular drinks and chocolate bars, as well as in coffee and tea, caffeine is believed to be the most widely ingested chemical during pregnancy. Conflicting results from studies concerning the effects of caffeine consumption by expectant mothers have been reported. It appears that the relationship between low to moderate consumption of caffeine and fetal abnormalities or complications of pregnancy have not been established. However, low birth weight infants and spontaneous abortion might be associated with caffeine ingestion. Pregnant females should be advised to refrain from heavy intake of coffee, tea, beverages and foods that yield 300 mg of caffeine daily. In 1980, the FDA recommended that pregnant women avoid the ingestion of

caffeine.

Smoking: It has been estimated that over fourteen million women between the ages of 18 and 44 smoke cigarettes. Studies have shown that cigarette smoking may result in increased fetal, neonatal and infant mortality, low birth weight of infants and complications during pregnancy. The detrimental effects of smoking appear to be dose-related. Smoking less than one pack a day resulted in a 20% increase in the risk of fetal mortality, whereas smoking more than one pack a day caused an increase of 35%. An increase in low birth weight is associated with the degree of smoking. Pregnant women should be advised as to the importance of smoking cessation at least during pregnancy.

Alcohol: Alcohol consumption during pregnancy can produce a group of fetal abnormalities known collectively as fetal alcohol syndrome (FAS). This is characterized by intrauterine and postnatal growth retardation, a characteristic pattern of facial features, CNS abnormalities, behavioral abnormalities or mental retardation. As the child ages, the facial changes may become less apparent, but short stature, microcephaly and behavioral abnormalities may persist. These problems are often experienced in children whose mothers consumed the equivalent of 2-3 ounces of absolute alcohol (4-6 drinks of hard alcoholic beverages) per day throughout pregnancy, or with binge drinking (6 or more drinks on one occasion per month). Moderate consumption (more than one ounce of absolute alcohol per week) may result in low birth weight, spontaneous abortion and impaired motor and mental development. Consumption of one to two drinks daily may be associated with growth-retarded babies. It has been estimated that about 20% of pregnant females consume some alcoholic beverages during pregnancy, but only 1-2 % consume 4 or more drinks daily. The incidence of FAS is 1 per 1000 live births, and about 4% of women who consume alcohol heavily may give birth to infants with FAS.

The mechanism of fetal abnormalities induced by alcohol is unknown. It is possible that ethanol, or its metabolite acetaldehyde, may directly or indirectly affect neuronal and nonneuronal brain cells.

Opioids: The incidence of opioid intake during pregnancy is relatively significant. About 0.2% of pregnant women are heroin or methadone users, and up to 75,000 babies annually receive opioids in utero. Growth retardation involving weight and length are encountered in infants exposed to opioids. Additionally, neonatal withdrawal syndrome characterized by hyperirritability, GI disturbances, respiratory distress, and seizures may be encountered. Acute heroin withdrawal symptoms occur within 24 hours, whereas that of methadone is mostly delayed in nature.

Cocaine: It is estimated that 1% of pregnant women in the USA use cocaine. In certain segments of the population, estimates may be as high as 15%. It is believed that about 100,000 babies are exposed to cocaine in utero. The most commonly encountered obstetric complications among users include placental abruption, premature delivery, and uterine rupture. Other effects include cerebral infarction, seizures and intrauterine growth retardation. Congenital malformations especially those involving the cardiovascular and genitourinary systems have been reported. Other studies failed to observe any significant abnormalities.

COMMON DISORDERS AND DRUGS USED SAFELY DURING PREGNANCY

Acne: Topical treatment using erythromycin, clindamycin, tretinoin, and benzoyl peroxide are recommended. The use of isotretinoin is contraindicated in pregnancy. Before its introduction in the USA, this drug was known to possess teratogenic effects in animals. The retinoid pregnancy prevention program was established to help prevent the occurrence of fetal malformation in humans. The program requires women to sign a consent form stating that they agree to use two effective methods of contraception before initiation of isotretinoin therapy.

Allergic Rhinitis: Topical use of glucocorticoids, decongestants and cromolyn is recommended. These preparations provide symptomatic relief without causing significant systemic absorption.

Constipation: Constipation may be encountered during pregnancy mainly due to the decreased GI motility and increased intestinal transit time. Expectant mothers should be encouraged to increase the amounts of fiber in the diet. Bulk-forming laxatives containing psyllium are recommended because of their safety and efficacy. Irritant laxatives must be avoided. Stool softeners such as docusate sodium provide relief of constipation and may be used during pregnancy. Caution should be exercised when using mineral oil, since it may interfere with absorption of lipid soluble vitamins.

Common Cold: Cold preparations usually consist of a combination of two or more drugs such as analgesics, antihistamines, and decongestants. Preparations containing chlorpheniramine are considered safe. However, brompheniramine should be avoided in the first trimester because of the risk of birth defects.

The use of sympathomimetic amines as decongestants during the first trimester may cause malformation such as club foot and inguinal hernia. Phenylpropanolamine may cause physical deformities of the eye and ear when used in the first trimester, and thus use should be avoided. Nasal administration of decongestants will minimize systemic exposure of the fetus to these drugs.

No potential risk has been reported following the use of the antitussive dextromethorphan and the expectorant guaifenesin. The use of iodides as expectorants should be avoided, since they may cause goiter in the fetus.

USE OF DRUGS DURING LACTATION

During the last 30 years, breast-feeding has gained popularity, and currently it is more prevalent than in past years. In 1995, about 60% of new mothers in the USA were breast-feeding at hospital discharge. Breast-feeding plays an important role not only in preventing infant mortality, but in morbidity from infectious diseases and in decreasing the risk of immunologically mediated disorders. Even though human milk is ideal for providing total nutritional needs to the growing infant, there are certain conditions that may require the use of formulas. Refraining from breast-feeding should be based on the fact that the risk to the infant outweighs the advantage of breast-feeding.

The increasing prevalence of breast-feeding has caused clinicians to direct their attention to the potential of harmful effects to infants from drugs taken by the nursing mother. There are several factors that play a role in determining the amount of drugs excreted in the mother's milk.

1. Characteristics of the drug: Most drugs cross mammary alveolar membranes by passive diffusion; others may pass through the aqueous-filled pores or by carrier mediated transport. The factors that determine the extent of diffusion of the drug into the breast milk include plasma protein binding, molecular weight of the drug, ionization and lipophilic nature of the drug.

   In order for a drug to cross any biological membrane, it must be present in the free form. Thus, drugs that are highly protein bound may be excreted in breast milk in low quantities. Highly protein bound drugs such as warfarin are incapable of crossing the mammary membrane in appreciable amounts. Drugs whose molecular weight is large (i.e., insulin, heparin) will not be excreted into breast milk.

   The pH of breast milk, which is about 7.00, is somewhat more acidic than plasma.

   Consequently, acidic drugs will occur as ionized molecules in the plasma and will fail to diffuse into breast milk. In contrast, basic drugs will be available as non-ionized molecules in the plasma and will be able to cross the membrane and reach the milk compartment.

   In addition to protein, minerals and lactose, the milk of nursing mothers is rich in fat.

   Lipophilic drugs may bind to milk causing accumulation of the drug in the milk.

2. Characteristics of Infant: Age of an infant is an important consideration. The younger the infant, the more potential for a stronger response to drugs, especially when the kidneys and liver are not functioning effectively.

3. Frequency of feeding the infant has an effect on the amount of drug reaching the milk. Infants who are breast fed frequently and for long periods, as it happens in the early neonatal stage, will be more exposed to drugs than infants who are breast fed less frequently, as is the case with older infants or infants who receive solid food supplements.

4. Another important consideration is the gastric emptying rate of infants. Infants who are breast-fed have a considerably shorter gastric emptying rate than infants who are bottle-fed. This results in reduction of exposure time of the drugs.

5. The drug regimen of the nursing mother may contribute to the amount of drug reaching milk. Feeding the infant one hour after drug intake, when it is at peak level in the mother's plasma and milk compartment will result in exposing the infant to larger quantities of the drug.

6. Another consideration is whether the drug product ingested by the lactating mother is a long or short acting medication. Long-acting drugs pose more risk to infants than short-acting medications.

7. Nature of the drugs taken can play a role in drug effect. If the drug taken by the nursing mother can be given to infants, then it is unlikely that the amount of drug reaching milk will exceed the pediatric therapeutic dose. Such drugs are safe to use during lactation. However, if the drug taken by the mother is not recommended for infants, then there is a risk potential for harmful effects to breast-feeding the baby.

DRUG ASSESSMENT OF RISK BEFORE BREASTFEEDING

The following is information regarding the risk for adverse effects that may be caused by some drugs to infants as a result of exposure to drugs in breast milk:

Aspirin: Metabolic acidosis, bleeding as a result of the effect on platelet function and Reye syndrome.
Phenobarbital: Sedation and possible spasm after cessation of breast-feeding
Acebutolol: Hypotension and bradycardia
Primidone: Sedative
Sulfasalazine: Bloody diarrhea
Ethanol: Large doses may cause a decreased milk ejection reflex in mothers, drowsiness and decreased growth and weight in infants.
Caffeine: High caffeine consumption may cause irritability and irregular sleep.
Methotrexate: Immunosuppression and neutropenia
Fluoxetine: Colic
Doxepin: Sedation
Tetracycline: Even though tetracycline-induced teeth discoloration of breast-fed infants has not been reported, the potential risk needs to be taken into consideration.
Diazepam: Poor weight gain.
Alprazolam: Withdrawal symptoms after discontinuation of breast-feeding
Bromocriptine: Suppression of milk production.
Theophylline Irritability
Androgens: Suppression of milk production
Ergot Derivatives: Suppression of milk production
Thiazide Diuretics: Suppression of milk product
Nicotine: Diarrhea, vomiting and restlessness
Amphetamine, Cocaine, Marijuana and Heroin: Intoxication

SUMMARY

The use of medications and chemicals during pregnancy and breast-feeding may pose potential risks to the developing fetus and the newborn. Although drugs probably account for no more than 1% of all human fetal malformation, and most of them carry a low-level risk, patient education and psychological support is essential. Appropriate management of the potential risks should be carefully considered.

A large number of drugs may be excreted in the breast milk and ingested by the newborn. Selection of the appropriate drug should be based on the drug properties, status of the infant and needs of drug administration.

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Please fill-out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Please rate each of the following from 1 to 7. Circle your choices. (1 is the lowest rating; 7 is the highest).

	Poor			Average			Excellent
1. Relevance of topic to practice.	1	2	3	4	5	6	7
2. Author's ability to communicate.	1	2	3	4	5	6	7
3. Author's knowledge of topic.	1	2	3	4	5	6	7
4. Appropriateness of topic.	1	2	3	4	5	6	7

5. Do you have any further comments about this lesson? _____

_____

Please Select the Most Correct Answer

1. Which statement is not correct regarding breast feeding?
   A. Provides total nutrients
   B. Decreases potential for immunological disease
   C. Refraining from breast feeding may be based on the fact that the risk to infant outweighs the advantage
   D. Being replaced by bottle feeding
2. A drug that may cause fetal malformation in animals may fail to give the same results in humans.
   A. True B. False
3. The category that shows risk of birth defects, but the potential benefits of the drugs may justify the potential risk, is:
   A. Category B
   B. Category C
   C. Category D
   D. Category X
4. Isotretinoin:
   A. Has no teratogenic effect on human fetuses
   B. May cause human fetal malformations
   C. Can be taken during pregnancy in low doses
   D. Can be given to pregnant women if ingested concurrently with pyridoxine
5. Which of these antiemetics has been associated with fetal jaundice and extrapyramidal symptoms when taken during pregnancy?
   A. Dimenhydrinate
   B. Chlorpromazine
   C. Meclizine
   D. Promethazine
6. Which of these is not characteristic of fetal alcohol syndrome?
   A. Intrauterine & postnatal growth retardation
   B. Changes in facial features
   C. Increased appetite
   D. Microcephaly
7. Which factor does not influence drug transport through the placenta?
   A. Plasma protein binding
   B. Lipophilic nature of the drug
   C. Molecular weight of the drug
   D. Age of the expecting female
8. Which statement is not correct regarding breast feeding?
   A. Breast milk contains low levels of fat
   B. pH of breast milk is strongly basic
   C. Breast fed babies have longer gastric emptying time than bottle fed babies
   D. Low molecular weight drugs are excreted in the mother's milk
9. Exposure of infants to aspirin in breast milk may cause:
   A. Metabolic acidosis
   B. Bradycardia
   C. Spasm after cessation of breast feeding
   D. Suppression of milk
10. Which statement is correct regarding mammary alveolar membrane absorption?
    A. Most drugs do not cross the barrier
    B. All drugs pass through the membrane via carrier mediated transport
    C. Most drugs cross the membrane via passive absorption
    D. Diffusion of drugs into breast milk occurs only through the aqueous filled pores

May, 2001 "Drugs in Pregnancy & Lactation—Part II" Volume 23, #5

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Pharmacists completing this course by May 31, 2004 may receive full credit.
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This lesson furnishes 1.25 hours (0.125 CEUs) of credit.

Program ID #707-000-01-005-H01.