PROGESTERONE vs. PROGESTINS

Natural Progesterone is the term used for the human-made hormone chemically indistinguishable from that produced in the body. It is not manufactured in a test tube from inorganic chemicals but is derived from a natural vegetable precursor such as soy or wild Mexican yam. Because natural progesterone (which is bio-identical to that found in the human body) comes from plants it cannot be patentable.

Pharmaceutical companies profit and marketability, however, are dependent on patentable molecules and compounds. By the 1950's when hormone production became more available, manufacturers were vying with each other to discover a cheap and patentable method of delivering hormones which could be taken orally. In Europe the drugs became known as progestogens and in America, progestins. There is still today confusion among healthcare providers that natural progesterone and progestins have the same benefits and side effects. This misconception seriously affects the health and well being of women of all ages, because progestins all have significant side effects such as blood clots, strokes and an increased risk of breast cancer. One of the most obvious differences is that natural progesterone promotes and sustains pregnancy; synthetic progestins state on their medical data sheet that they may increase the risk of miscarriage or congenital deformities of the fetus. Synthetic, chemically altered hormone drugs occupy cell receptors and the messages they convey may be different and even contrary to the hormone they are meant to stimulate. Because they are foreign to our bodies they cannot be excreted well.

Progestins are similar to progesterone and estrogen in their ability to be easily absorbed into the body transdermally, however, they're more commonly prescribed in oral tablets which then have to undergo the first pass of the liver (causing unnecessary work and strain on this organ) Progestins like estrogen cause water retention, often accompanied by high blood pressure. Progesterone helps the body to use and eliminate fats, but progestins have the opposite effect. (This is usually seen in weight gain after starting birth control pills or hormone replacement therapy) Progestins share with natural progesterone the ability to promote new bone formation but with less success. Dr Jerilynn Prior found a 5% increase using provera in postmenopausal osteoporotic patients, however, Dr. John Lee typically saw 15% bone density increase with natural progesterone.

THE OBVIOUS DIFFERENCES:

- Why do fertility doctors always use progesterone and not progestins?
- Why do progestins cause birth defects, while progesterone is essential for a viable and healthy pregnancy?
- Why don't synthetic progestins show up in blood and saliva tests for progesterone levels? In other words, why doesn't taking a progestin raise progesterone levels?
- Pregnant women are making 300 + mg of progesterone daily in the last trimester. Why don't they have higher rates of breast cancer?
- Why doesn't natural progesterone cause the side effects listed for medroxyprogesterone acetate (provera), the most commonly used synthetic progestin for HRT?

NATURAL PROGESTERONE VS SYNTHETIC PROGESTINS

Effects	Natural (Real) Progesterone	Synthetic Progestin
May cause bloating		√
Breast tenderness		√
Decrease in sex drive		√
May cause depression		√
Increases risk of birth defects		√
Causes facial hair and loss of scalp hair		√
May cause stroke, heart attack, blood clots		√
Causes change in blood sugar		√
Increase in vaginal yeast infections		√
Increase in headaches and migraines		√
Causes acne, skin rashes		√
Increases risk of cancer of the breasts		√
Prevents implantation of fertilized egg		√
Protects against breast, ovarian and uterine cancer	√	Uterus only
Restores libido	√	
Regrowth of scalp hair	√	
Natural diuretic, burns fat	√	
Improves in vitro fertilization	√	
Improves bone density	√	
Relieves PMS and Menopause symptoms	√	Modestly
Relieves vaginal dryness	√	
Facilitates thyroid hormone	√	
Antidepressant action	√	
Improves fibrocystic breasts	√	
Essential for successful pregnancy	√	
Reduces fibroids of the uterus	√	
Helps sleep disturbances	√	
A precursor to estrogen and testosterone	√	
Essential for males, prostate health	√	

References:

Dr John Lee, M.D. What Your Doctor May Not Tell You About Menopause

Depo-Provera Contraceptive Injection Medroxyprogesterone Acetate Injectable Suspension, USP Patient Pamphlet Pharmacia and UpJohn Feb 1999

Natural Progesterone Cream, Safe and Natural Hormone Replacement C. Norman Shealy, M.D., Ph.D.

Prior, J.C. 1990 Progesterone as a Bone-trophic Hormone, Endocrine Reviews. 11:386-98

PDR 2000 pg 1878 - 1882

Article by James N. Brenner, M.A., G.N.P. - B.C.
Co-Authored by Linda Brenner, Womens Health Educator

Noriday Tablets

Table of Contents

PATIENT INFORMATION LEAFLET

Noriday®
Norethisterone

Please read this leaflet carefully before you start to take your pills. The leaflet can't tell you everything about Noriday, so if you have any questions or are not sure about anything, ask your doctor, clinic or pharmacist. Keep this leaflet. You may need to read it again.

Some information about Noriday

The name of your medicine is Noriday. It contains norethisterone, a type of hormone called a 'progestogen'. Noriday is a progestogen-only contraceptive pill, or 'POP' for short. The only hormone it contains is progestogen, unlike the combined contraceptive pill which contains two types of hormones - oestrogen and progestogen.

What is in Noriday?

Each Noriday pill contains:

350 micrograms of norethisterone, and inactive ingredients: maize starch, polyvidone, magnesium stearate and lactose.

Noriday pills are white and have 'SEARLE' written on one side and 'NY' on the other side. They are packed in blister strips and supplied in packs of 84 pills.

Who supplies Noriday?

Pharmacia Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Who makes Noriday?

Pharmacia Limited

Morpeth
Northumberland
NE61 3YA
United Kingdom

What is Noriday for?

Noriday helps to prevent you becoming pregnant. It does this in several ways. It thickens the fluid at the entrance to the womb. This makes it hard for sperm to travel through and enter the womb. It also changes the lining of your womb so that a fertilised egg cannot grow there. Sometimes it stops your ovaries releasing an egg.

Before you take Noriday

Noriday may not be suitable for all women. Do not take Noriday if you have ever had any of the following:

- cancer of the breast, cervix, vagina, or womb
- malignant or benign liver tumours
- liver problems, for example jaundice (yellowing of the skin or eyes)
- pruritus (itching all over your body) or jaundice while you were pregnant
- high levels of fat in your blood
- vaginal bleeding for which your doctor could not find the cause
- amenorrhoea (lack of periods)
- thrombophlebitis (inflamed veins), coronary artery disease, heart attack, angina, blood clots, or a stroke
- a disease of your red blood cells, such as sickle cell anaemia
- an allergic reaction to any of the ingredients in Noriday

Also, please tell your doctor if you could be pregnant. You should not be taking Noriday if there is a possibility that you may be pregnant.

Tell your doctor if you suffer from any of the following conditions, as some diseases may get worse when you are taking the contraceptive pill.

- epilepsy
- heart or kidney problems depression
- diabetes
- gallstones
- high blood pressure
- multiple sclerosis
- otosclerosis (an inherited form of deafness which may get worse during pregnancy)
- migraine
- depression
- varicose veins
- asthma
- tetany (muscle twitches)
- porphyria (a rare inherited blood disease)

What do I do if I become pregnant whilst taking Noriday?

If you suspect that you might be pregnant, seek confirmation and see your doctor immediately. Stop taking the tablets and use another method of contraception until you are sure that you are not pregnant.

Noriday can increase your risk of having an ectopic pregnancy (a pregnancy developing outside of the womb).

The exposure of the foetus to sex hormones such as Noriday has been shown to be associated with an increased rate of birth defects such as heart and limb malformations. Please discuss how advisable a continuation of any pregnancy under Noriday is with your doctor.

What do I do if I am changing pill brands?

Take the first pill of your new pack on the day after you finish your old pack. Do not leave any break at all.

What do I do if I have a stomach upset or I am sick?

Noriday may not work if you are sick or have diarrhoea. Continue to take your pills as normal but use a condom while you are ill and for the next seven days.

What do I do if I am having an operation or become immobilised?

If you are going to have an operation, or if you are ill or injured and there may be a risk of blood clots, please mention to your doctor that you take Noriday. Noriday should be discontinued 4 weeks prior to surgery and can normally be re-started 2 weeks following surgery. Your doctor will discuss what is relevant for you.

What do I do if I have just had a baby?

You can use Noriday after having a baby whether you are breast feeding or not. You can start taking the pill from day 21 after childbirth. This protects you as soon as you have taken the first pill. If you start later than this you may not be protected until you have taken the pill for another seven days. If you have had a miscarriage or abortion you can start taking the pill straightaway and will be protected immediately.

What do I do if I want a baby?

If you want to have a baby it is helpful to wait until your regular periods return before you try to get pregnant. Therefore it is recommended that you stop taking Noriday tablets three months before a planned pregnancy. You can use another type of contraceptive, such as a condom until then. Once you have had a period it will be easier to work out when the baby is due. However, if you get pregnant as soon as you stop taking Noriday, this is not harmful.

Does Noriday have side effects?

PRODUCT INFORMATION

MICRONOR® TABLETS
norethisterone

Actions

Progestogen-only oral contraceptive containing norethisterone, a synthetic progestogen.

The primary mechanism through which norethisterone prevents conception is not known, but progestogen-only contraceptives are known to alter the cervical mucus, increasing the difficulty of sperm penetration, exert a progestational effect on the endometrium interfering with implantation, and in some patients, suppress ovulation.

Norethisterone is rapidly absorbed from the gastrointestinal tract. Following oral administration, metabolites appear in the urine as conjugated glucuronides and sulphates, with unconjugated metabolites appearing in the faeces.

Pregnancy rates. The pregnancy rate in women using conventional combination oral contraceptives (containing 35 micrograms or more of ethinyloestradiol or 50 micrograms or more of mestranol) is generally reported as less than 1 pregnancy per 100 woman-years of use. Slightly higher rates (somewhat more than 1 pregnancy per 100 woman-years of use) are reported for some combination products containing 35 micrograms or less of ethinyloestradiol, and rates of the order of 3 pregnancies per 100 woman-years of use are reported for the progestogen-only oral contraceptives.

These rates are derived from separate studies conducted by different investigators in several population groups and cannot be compared precisely. Furthermore, pregnancy rates tend to be lower as clinical studies are continued, possibly due to selective retention in the longer studies of those patients who accept the treatment regimen and do not discontinue as a result of adverse reactions, pregnancy or other reasons.

In clinical trials with MICRONOR, 2,963 patients completed 25,901 cycles of therapy and a total of 55 pregnancies were reported. This represents an average pregnancy rate of 2.54 per 100 woman-years. A higher pregnancy rate of 3.72 was recorded in fresh patients (those who had never taken oral contraceptives prior to starting MICRONOR therapy), to a large extent because of incorrect tablet intake. This compares to the lower pregnancy rate of 1.95 recorded in changeover patients (those switched from other oral contraceptives.) This difference was found to be statistically significant. Further more, an even greater statistically significant difference in pregnancy rates between two groups found during the first six months of MICRONOR therapy. Therefore it is especially important for fresh patients to strictly adhere to the regimen.

MICRONOR tablet contains the inactive ingredients: lactose anhydrous, magnesium stearate and pregelatinised maize starch.

Indications

Oral contraception.

7. Birth Defects of Offspring

The use of female sex hormones - both oestrogenic and progestational agents - during early pregnancy may seriously damage the offspring. An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of sex hormones, including oral contraceptives, in pregnancy.

8. Gallbladder Disease

Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives and oestrogens.

9. Carbohydrate and Lipid Effects

A decrease in glucose tolerance has been observed in a significant percentage of patients on oral contraceptives. For this reason, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

10. Bleeding Irregularities

Breakthrough bleeding, spotting, and amenorrhoea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, as in all cases of irregular bleeding from the vagina, nonfunctional causes should be borne in mind. In undiagnosed persistent or recurrent abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

11. Ectopic Pregnancy

Ectopic as well as intrauterine pregnancy may occur in contraceptive failure.

12. Use in Nursing Mothers

If feasible, the use of oral contraceptives should be deferred until the infant has been weaned. A small fraction of the active ingredients of oral contraceptives have been identified in the milk of mothers receiving these drugs. The effect of these on the infant is unknown. There may be a decrease in the quantity and quality of the milk.

Precautions

1. Before prescribing oral contraceptives, a complete medical and family history and physical examination is desirable, including special reference to blood pressure, breasts, abdomen and pelvic organs, including Papanicolaou smear and laboratory tests. As a general rule oral contraceptives should not be prescribed for longer than one year without another physical examination being performed.

2. The following are some of the medical conditions reported to be influenced by oral contraceptive therapy.

   a) Under the influence of oestrogen-progestogen preparations pre-existing uterine fibromyomata may increase in size.

   b) A decrease in glucose tolerance in a significant number of women. (See 'Warnings' 9).

ScienceLab.com
Chemicals & Laboratory Equipment

Material Safety Data Sheet
Norethindrone Acetate MSDS

Section 1: Chemical Product and Company Identification

Product Name: Norethindrone Acetate

Catalog Codes: SLN1585

CAS#: 51-98-9

RTECS: RC8965000

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym: 19-Norethisterone acetate, 19-Norethynyltestosterone acetate, Milli-Anovlar, Norethindrone 17-acetate, Norethisteron acetate, Norethynyltestosterone acetate, Norethysterone acetate, Norlutate, Norlutin A, Norlutine acetate, Orlutate, Primolut-Nor, Progylut, SH 420; (17-alpha)-17-(Acetyloxy)-19-norpregn-4-en-20-yn-3-one; 17-Acetoxy-19-nor-17-alpha-pregn-4-en-20-yn-3-one; 17-Acetyloxy(17-alpha)-19-norpregn-4-estren-17-beta-ol-acetate; 17-alpha-Ethinyl-19-nortestosterone acetate; 17-alpha-Ethinyl-19-nortestosterone-17-beta-acetate; 17-alpha-Ethynyl-17-beta-acetoxy-19-norandrost-4-en-3-one; 17-alpha-Ethynyl-17-hydroxyestr-4-en-3-one acetate; 17-alpha-Ethynyl-19-nortestosterone acetate; 17-beta-Acetoxy-19-nor-17-alpha-pregn-4-en-20-yn-3-one; 17-beta-Hydroxy-19-nor-17-alpha-pregn-4-en-20-yn-3-one acetate; 17-Hydroxy-19-nor-17-alpha-pregn-4-en-20-yn-3-one acetate

Chemical Name: 19-Nor-17-alpha-pregn-4-en-20-yn-3-one, 17-acetoxy-

Chemical Formula: C22-H28-O3

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Norethindrone Acetate	51-98-9	100

Toxicological Data on Ingredients: Norethindrone Acetate LD50: Not available. LC50: Not available.

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant).

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer). CARCINOGENIC EFFECTS: Classified 2A (Probable for human.) by IARC. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Classified POSSIBLE for human. DEVELOPMENTAL TOXICITY: Not available.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Slightly explosive in presence of open flames and sparks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

atility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Insoluble in cold water, hot water.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials, dust generation

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Not available.

Special Remarks on Reactivity:
Air sensitive. Moisture sensitive. Avoid exposure to air or moisture over long periods of time.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
LD50: Not available. LC50: Not available.

Chronic Effects on Humans:
CARCINOGENIC EFFECTS: Classified 2A (Probable for human.) by IARC. TERATOGENIC EFFECTS: Classified POSSIBLE for human.

Other Toxic Effects on Humans:
Hazardous in case of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant).

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:
May cause adverse reproductive effects and birth defects (teratogenic). May cause cancer based on animal test data. (IARC Cancer Review: Animal Limited and Sufficient Evidence). May affect genetic material (mutagenic)

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation with nausea, vomiting, cramping, abdominal pain and unusual thirst. May affect behavior/central nervous system. Other symptoms may include tiredness, dizziness, headache, insomnia, nervousness, mood changes, mental depression, unconciousness, hot flashes, swelling of the ankles. Chronic Potential Health Effects: Skin: Prolonged or repeated skin contact may cause allgeric dermatits/skin rash in sensitized persons. Ingestion: Prolonged or repeated ingestion may affect endocrine system (menstrual irregularities and unexplained flow of breast milk, breast pain and tenderness in women, and gynecomastia in men), and liver (jaundice, hepatitis) and may cause loss or gain of hair, weight gain or weight loss, blood clots, porphyria, and loss of sexual desire. May have androgenic and anabolic action. Ingestion or Inhalation: Possible allergic reaction to material if it is inhaled or ingested.

Section 12: Ecological Information

.cotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations:
California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Norethindrone Acetate California prop. 65: This product contains the following ingredients for which the State of California has found to cause birth defects which would require a warning under the statute: Norethindrone Acetate Illinois chemical safety act: Norethindrone Acetate

Other Regulations:
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R36- Irritating to eyes. R45- May cause cancer. R63- Possible risk of harm to the unborn child. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label. S53- Avoid exposure - obtain special instructions before use.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0