NORPLANT SYSTEM

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Prescribing Information

DESCRIPTION

The NORPLANT SYSTEM kit contains los verbicon capsules, a set of six flexibly closed capsules made of silicone rubber taking 50 mg depot medroxyprogesterone acetate (DMPA) by injection. The capsules are designed to be surgically implanted subcutaneously in the skin of the female upper arm. The capsules are made from a combination of silicone rubber and plastic. The device consists of six capsules, each containing 30 mg of DMPA. The capsules are placed subcutaneously in the skin of the upper arm. The capsule is a flexible, subcutaneous implant containing DMPA, a synthetic progestin.

INDICATIONS AND USAGE

NORPLANT SYSTEM is a long-term method of contraception, this is reported as long-term (up to 5 years) reversible contraceptive system. The capsules

CONTRAINdications

1. Active thrombophlebitis or thromboembolic disorders. There is insufficient information regarding women who have had previous thromboembolic disease.

ADVERSE REACTIONS

6. Ocular Lesions

Autoimmune diseases such as scleroderma, systemic lupus erythematosus should be assessed by an ophthalmologist. Consideration should be given to removing NORPLANT SYSTEM capsules in patients with these conditions which might be aggravated by fluid retention.

FUNCTIONAL CLASS

A. 6.

7. Use Before or During Early Pregnancy

INSTRUCTIONS FOR INSERTION AND REMOVAL—Removal Procedure

NORPLANT SYSTEM capsules should be removed from women who are using the NORPLANT SYSTEM method of contraception and who have been scheduled for any form of surgery, including removal of pregnancy. If removal of the capsules is necessary, it should be performed by a trained health-care provider who is familiar with the NORPLANT SYSTEM.

PRECAUTIONS

6. Pregnancy

NORPLANT SYSTEM capsules should be used for up to 5 years. After the last capsule is used, the patient should be counseled that the product is no longer effective and that she may be pregnant. The patient should be informed that the product is not effective in preventing sexually transmitted diseases, including HIV/AIDS.

NORPLANT SYSTEM capsules are not intended for use in women who are pregnant or breastfeeding. Women who are pregnant or breastfeeding should use a nonhormonal contraceptive method. Women who are pregnant or breastfeeding should be advised that the NORPLANT SYSTEM should not be used if they are pregnant or breastfeeding.

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ADVERSE REACTIONS

The following adverse reactions have been associated with the NORPLANT SYSTEM:

- Infrequent: breast discharge, abdominal discomfort
- Rare: breast tenderness

In addition, the following adverse reactions have been reported post-marketing:

- Scanty bleeding
- Many bleeding days or prolonged bleeding

ADVERSE REACTIONS (in situ)

- Breast discharge
- Abdominal discomfort

Myocardial infarction

- Phlebitis

Pulmonary embolism

Stroked

In addition, the following adverse reactions have been reported with a frequency of less than 1% and are possibly related to NORPLANT SYSTEM:

- Nausea/vomiting
- Mastalgia

WARNINGS AND PRECAUTIONS

1. Scalpel
2. Packages of gauze sponges
3. NORPLANT SYSTEM trocar
4. Package of skin closures
5. Alcohol, iodine, povidone-iodine

The plastic cover and tray are NOT STERILE.

The tip of the trocar is now at a distance of 4.5 cm long, to mimic the fanlike position of the implanted capsules.

The trocar has two marks on it. The first mark is closer to the hub and indicates how far the trocar should be introduced during the insertion.

The second mark is close to the tip and indicates how much of the trocar should remain under the skin following the insertion of each capsule.

The gauze may be removed after 1 day, and the arm to ensure hemostasis.

After placement of the sixth capsule, if required.

Do not force the trocar, and if resistance is felt, by another technic.

INSTRUCTIONS FOR INSERTION AND REMOVAL

The NORPLANT SYSTEM consists of six sponge-filled capsules that are placed subdermally in the arms at the upper inner arms.

The NORPLANT SYSTEM provides up to 5 years of effective contraceptive protection.

The base of the insertion site and removal of the NORPLANT SYSTEM capsule is to be performed under aseptic conditions using a sterile technique.

NORPLANT SYSTEM capsules are to be removed when the patient requests, or when the patient returns for another visit.

The remaining capsule(s) will be easier to remove after the area is healed.

The position of the patient and the anesthetics are the same as for insertion.

INSTRUCTIONS FOR INSERTION

1. Scalpel
2. Packages of gauze sponges
3. Syringe
4. Forceps (straight and curved)

Steady at temperature away from excess heat and moisture.

REFERENCE available upon request.

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