Organometril contains lynestrenol, a progestagen similar to the natural hormone progesterone. Progestagens, as in Organometril, are often prescribed for disturbances of the menstrual cycle. Organometril can also be prescribed:

- for premenstrual syndrome (the regular occurrence of one or more complaints in the period before the menstruation);
- for endometriosis (abnormal growth of the lining of the uterus);
- for treatment of endometrial cancer;
- for the treatment of certain disorders of the breast;
- to suppress the release of an egg cell (ovulation) or menstruation;
- as an adjunct to estrogen therapy during or after the menopause.

2. BEFORE YOU TAKE ORGANOMETRIL

Do not take Organometril if you

- are pregnant or think you may be pregnant;
- have a severe liver disease such as jaundice, inflammation of the liver (hepatitis), tumors of the liver, the rare liver diseases Rotor syndrome or Dubin-Johnson syndrome, or when the liver has not completely recovered from such a severe condition;
- have abnormal vaginal bleeding, which has not been evaluated by your doctor;
- have conditions that deteriorated during pregnancy or during previous use of hormones like: jaundice, severe itching, skin rash (herpes gestationes), a metabolic disease of the liver (porphyria), or a heritable form of hearing loss (otosclerosis);
- are hypersensitive to Organometril or one of its ingredients.

Take special care with Organometril

Regular examination by your doctor can be necessary in some cases.

Therefore it is important to tell your doctor if you have or have had any of the following conditions:

- blood clotting disorder (e.g. thrombosis)
- heart or blood vessel disease
- severely depressed mood
- liver disease, such as jaundice, or a tumor in the liver
- abnormal vaginal bleeding
- high cholesterol or other lipids in the blood
- chloasma (brown, blotchy spots on the skin often appearing during pregnancy)
- acne, seborrheic skin and increased body or facial hair

Using other medicines

Other medicines may influence the effects of Organometril, or Organometril may affect other medicines. Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are using, or are about to use, one of the following medicines:

- rifamycins or troleandomycin (medicines for bacterial infections)
- hydantoins, barbiturates and carbamazepine (medicines for epilepsy)
- aminoglutethimide (medicine for treatment of Cushing syndrome)
- cyclosporine (medicine used after transplantation)
- theophyllines (medicine for asthma, bronchitis and emphysema)
- beta-adrenergic blockers (medicines for high blood pressure or heart conditions)
- insulin (medicine for diabetes)

Pregnancy and breast-feeding

If you are pregnant or you think you may be pregnant, do not take Organometril.

If you are breastfeeding, do not take Organometril without asking your doctor first.

Ask your doctor or pharmacist for advice before taking any medicine.
Orgametril for a number of days per month. A few days (often within three days) after completing the Orgametril course, the inner lining of the uterus will be shed. This is accompanied by a vaginal bleeding (like a normal menstruation).

4. POSSIBLE SIDE EFFECTS
Orgametril may cause side effects, depending on the dosage and sensitivity of the patient. The following side effects have been reported:
- Hypersensitivity
- Fluid accumulation in the tissues (fluid retention)
- Slightly increased blood sugar after a meal (reduced glucose tolerance)
- Changes in lipid and cholesterol levels in the blood
- Nervousness
- Depressed mood
- Increase or decrease of sexual desire (libido)
- Headache
- Migraine
- Dizziness
- Nausea
- Vomiting
- Abdominal pain
- Diarrhea
- Constipation
- Jaundice (icterus)
- Increased sweating
- Chloasma (pregnancy spots, i.e., patchy discoloration of the skin)
- Itching
- Oily skin (seborrhea)
- Acne
- Skin reactions
- Increased body or facial hair
- Vaginal bleeding (in between the normal periods) mainly during the first two months
- Sensitive breasts
- Absence of menstruation
- Change in vaginal secretion

If you notice any of these side effects contact your doctor, especially when you experience vaginal bleeding that has not been evaluated by your doctor. If you notice a side effect not mentioned in this leaflet or you experience a serious side effect, inform your doctor or pharmacist.

5. STORING ORGAMETRIL
Keep Orgametril out of reach and sight of children. Store at 2 - 30°C. Store in original package to protect from light and moisture. Do not use Orgametril after the date stated on the package following “do not use after” or “exp”.

6. FURTHER INFORMATION
What Orgametril contains
The active substance of Orgametril is lynestrenol. The other ingredients are potato starch, alpha-tocopherol, glycerol, magnesium stearate, talc and lactose monohydrate.
What Orgametril looks like and contents of the pack
White, round scored tablets marked “Organon” on one side; the other side is marked with the code “TT” above and the code “4” below the score line. 1 push-through strip with 30 scored tablets of 5 mg.