



Allygest[®]

Allylestrenol INN 5 mg

COMPOSITION:

Each tablet contains Allylestrenol INN 5 mg.

CHARACTERISTICS:

Allylestrenol is an oral Gestagen. In castrated animals, it has a potent pregnancy-maintaining action without producing hormonal side-effects, in particular no masculinisation of female foetuses.

Clinical studies have indicated that **Allygest[®]** stimulates the endocrine function of the trophoblast. In vitro, **Allygest[®]** stimulates the placenta to produce more progesterone. In patients with pregnancy at risk, abnormally low levels of placental hormones (HCG, HPL, oestrogens and progesterone) and some specific enzymes (oxytocinase, CAP) were found to be increased to normal during treatment. In the majority of patients with pregnancy at risk who were treated with **Allygest[®]** the threat of abortion was removed and pregnancy brought to term without complications. **Allygest[®]** is very well tolerated. Side-effects of any importance have not been observed.

PHARMACOLOGY:

Allylestrenol has been found to have a relatively weak progestational effect on the human endometrium. To obtain a full secretory endometrium in oestrogen-primed castrated women or to postpone menstruation (with an oestrogen added) in normal ovulating women, doses of allylestrenol were required which were higher than those recommended for the treatment/prevention of abortion.

In vitro studies have shown that allylestrenol stimulates the synthesis of progesterone in the human placenta. It also brought about a significant (p/ 0,01) increase in the production of some specific placental enzymes (cystine aminopeptidase (CAP) and heat-stable alkaline phosphatase).

Histological and histochemical changes indicating an increased activity have been found in the placenta, particularly in the syncytiotrophoblast of women with a normal and threatened pregnancy, treated with allylestrenol. The stimulatory effect of allylestrenol on placental function was also suggested by the increased level of placental hormones (pregnanediol, oestriol, HCG and HPL) and enzymes (oxytocinase, CAP) in the maternal urine and plasma, which followed the administration of the drug e.g. in the early weeks as well as in the last trimester of pregnancy.

A study in full-term pregnant women revealed that allylestrenol in high doses (up to 100 mg daily) did suppress the intensity of spontaneous uterine contractions, but had no effect on the sensitivity of the uterine muscle to oxytocin, and no adverse effect on the progress of normal delivery.

Studies in non-pregnant women with and without endocrinological disorders have shown that allylestrenol has no oestrogenic or androgenic properties and no adverse effects on the adrenal function.

No abnormal liver function tests or water and salt retention were observed in healthy female volunteers (non-pregnant) who were given allylestrenol.

INDICATIONS:

- ◆ Threatened abortion
- ◆ Habitual abortion
- ◆ Threatened premature labour
- ◆ Intra Uterine Growth Retardation (IUGR)
- ◆ Failure of nidation / Implantation

DOSAGE:

- ◆ **Threatened Abortion:** 1 tablet thrice daily for 5-7 days. The treatment period may be extended depending on necessity. After symptoms disappear, the dosage should be gradually reduced.
- ◆ **Habitual Abortion:** 1 to 2 tablets daily with the confirmation of pregnancy. Administration should be continued until at least one month after the critical period.
- ◆ **Threatened Premature Labour:** 40 mg daily until symptoms improve.
- ◆ **Intra Uterine Growth Retardation [IUGR]:** 1 tablet three times a day at least two months. Reduce the dose if symptoms improve.
- ◆ **Failure of Nidation / Implantation:** 2 - 4 tablets daily from 16th to 26th day of the cycle until conception is achieved.

CONTRAINDICATIONS:

- ◆ Breast Cancer or history of problem with the breasts like - Nodules, an abnormal Mammogram, or Fibrocystic Diseases.
- ◆ Severe liver disease such as Cholestatic Jaundice or Hepatitis, Hepatic Cell Tumours, Rotor Syndrome and Dubin Jhonson Syndrome.
- ◆ Undiagnosed vaginal bleeding
- ◆ Toxaemia of Pregnancy
- ◆ Crisis Seizures, Migraines

SIDE EFFECTS:

No major side effects have been reported. Gastrointestinal complaints like nausea, vomiting, epigastric discomfort have been reported occasionally.

SAFETY:

- ◆ It is free from anti-ovulatory and androgenic properties.
- ◆ Allylestrenol (**Allygest[®]**) produces no masculinization of female Foetus.

PRECAUTIONS:

Doctor should be consulted if the patient has cardiac or renal dysfunction, migraine, epilepsy, and asthma.

STORAGE CONDITION:

Store in a cool & dry place, away from light. Keep the medicine out of the reach of children.

COMMERCIAL PACK:

Allygest[®] Tablet: Each box contains 3x10 tablets in Alu-PVC blister strip.



Manufactured by:
Nuvista Pharma Limited
48 Tongi Industrial area, Gazipur, Bangladesh
A subsidiary of Beximco Pharmaceuticals Ltd.

1035DS1601