

Composition:

Each tablet contains allylestrenol INN 5mg.

Characteristics:

Gestrenol® is an orally active gestagen. Allylestrenol has a pronounced pregnancy maintaining action in castrated animals without producing hormonal side-effects. In the human, premature termination of pregnancy often follows a fall in the levels of placental hormones. Gestrenol® has been shown to stimulate the placental progesterone production in vitro and to promote the secretion of placental hormones (human chorionic gonadotrophin, human placental lactogen, estrogens and progesterone) and oxytocinase in patients with pregnancy at risk. In agreement to this the trophoblastic layers of the placenta show histological signs of activation. Clinical studies have indicated that Gestrenol® is an effective and safe pregnancy maintaining preparation.

Administration of **Gestrenol**[®] in combination with bed rest can remove or prevent the threat of abortion in early pregnancy or stop threatened premature labor. Gestrenol® is generally well tolerated. Serious adverse reactions have neither been reported in the mother nor in the offenring

Indications	Dosage:
Threatened abortion	1 tablet three times daily for 5-7 days. If necessary, the treatment period may be extended. After disappearance of the symptoms the dosage should be gradually reduced unless symptoms return.

Habitual abortion	1-2 tablets daily as soon as pregnancy has been diagnosed. The administration should be continued until at least one month after the end of the critical period.
Threatened premature labor	The dosage must be determined individually. High dosages (up to 40mg daily) have been used.

Administration:

Gestrenol® tablets should be taken orally.

Contra-indications:

There are no known contra-indications.

Warnings and precautions:

No warnings or precautions are applicable.

Adverse reactions:

Gastrointestinal complaints (nausea. vomiting) have been reported occasionally.

Commercial Supply:

Gestrenol® tablets are available in blister packs of 5 x 10 tablets.

Storage conditions:

Store in a cool and dry place, protected from light and moisture, temperature below 30°C.



C-Code: RO2/105214500/V01