



## Bioavailability and kinetic profile of injectable progesterone according to doses and administration ways

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Since several years progesterone supplementation in women undergoing ART has been consolidated by means of specific preparations and ways of administration (i.e. injectable oily formulation, vaginal). IBSA has recently developed a new aqueous progesterone formulation, intended for both s.c and i.m. administration with the aim of achieving an improvement in terms of local tolerability while maintaining adequate plasma concentrations.

Phase I clinical trials were carried out in order to obtain relevant information on the kinetic profile of the new progesterone aqueous product.

The evidences obtained with these studies provide data which allow evaluation of the new progesterone aqueous formulation selected as a part of infertility therapy. The **extent** of progesterone absorption (AUC<sub>0-t</sub>) is not affected by the different administered formulations. On the contrary the **rate** of progesterone absorption (C<sub>max</sub> and T<sub>max</sub>) is clearly influenced by both the formulation vehicles and the administration route. The new developed progesterone i.m. and s.c. aqueous formulation gave rise to peak serum concentrations about 4 and 3 times higher than the i.m. oily formulation while the peak concentrations were reached much earlier (on the average about 8 times faster).

The comparison of the main PK parameters obtained both after single and multiple administration of the selected s.c. aqueous formulation at different dose regimens (25, 50 and 100 mg single dose and 25 and 50 mg /day for 11 days) demonstrated the **dose proportionality** of progesterone bioavailability when administered within the expected therapeutic dose range.