Progesterone bioavailability data through buccal routes

We can use published literature data on pharmacokinetic parameters such as bioavailability to help guide our approximate starting dose selection for buccal film strips of progesterone.

Progesterone PK parameters for different routes are listed in the table below.

Parameter	Buccal Gel (US patent number: US20200129422A1)	Buccal Film proposed for IVIM	Oral Capsule (Prometrium®)	Vaginal Gel (Crinone® 8%)
Dose Range	60 mg	60 mg once daily or 30 mg twice daily	100–200 mg/day	90 mg (8%) per application
Systemic Bioavailability	Moderate to High (~50–75%)	Moderate to High (~50–75%) - estimated	Low (<10%)	Low (~10%)
Cmax	Up to 13–14 ng/mL	8–12 ng/mL (target therapeutic range)	~2–5 ng/mL	~1–2 ng/mL
Tmax	2–4 hours	1–3 hours	~2 hours	~6 hours
Duration of Effect	6–12 hours	6–12 hours	Short	Local effect dominant
Main Absorption Pathway	Transmucosal	Transmucosal (via film contact)	GI → Liver (first pass)	Local → Uterine targeting
Patient Compliance	High	Very High (discreet, precise)	Moderate	Moderate (can cause irritation)
Use Case Suitability	Systemic progesterone therapy	Systemic progesterone therapy	Hormone support	Localized endometrial support

Dose recommendations for Progesterone buccal film strips:

Drug name	Dose/film
Progesterone	30 mg & 60 mg
Estradiol and Progesterone	0.25 mg and 30 mg 0.5 mg and 30 mg 0.5 mg and 60 mg 1 mg and 60 mg 2 mg and 60 mg Any other combinations.

Reference:

Progesterone in Bioadhesive Formulation for Buccal Delivery; US patent number: US20200129422A1; 2019; refer figure 4 of the patent.