Important identified risk: Interference with contraception	
Evidence for linking the risk to the medicine	Interaction of Senstend with polyurethane causing decrease in its tensile strength. Patients are informed not to use polyurethane-based barrier contraceptives with Senstend.
Risk factors and risk groups	Patients or partners using polyurethane-based female or male condoms. Device interaction testing conducted with barrier contraceptives showed that the tensile strength of polyurethane devices (female and male condoms) was compromised, causing increased puncture rates. Devices made from latex rubber, polyisoprene, nitrile and silicone were unaffected. 1. Outcome will be unplanned pregnancy. 2. If the device suffers significant damage, it could increase the risk of sexually transmitted diseases.
Risk minimisation measures	Routine risk communication • SmPC section 4.4. Routine risk minimisation activities recommending specific clinical measures to address the risk: • SmPC section 6.2. • PL section 2.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies, which are conditions of the marketing authorisation or specific obligations of Senstend.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Senstend.