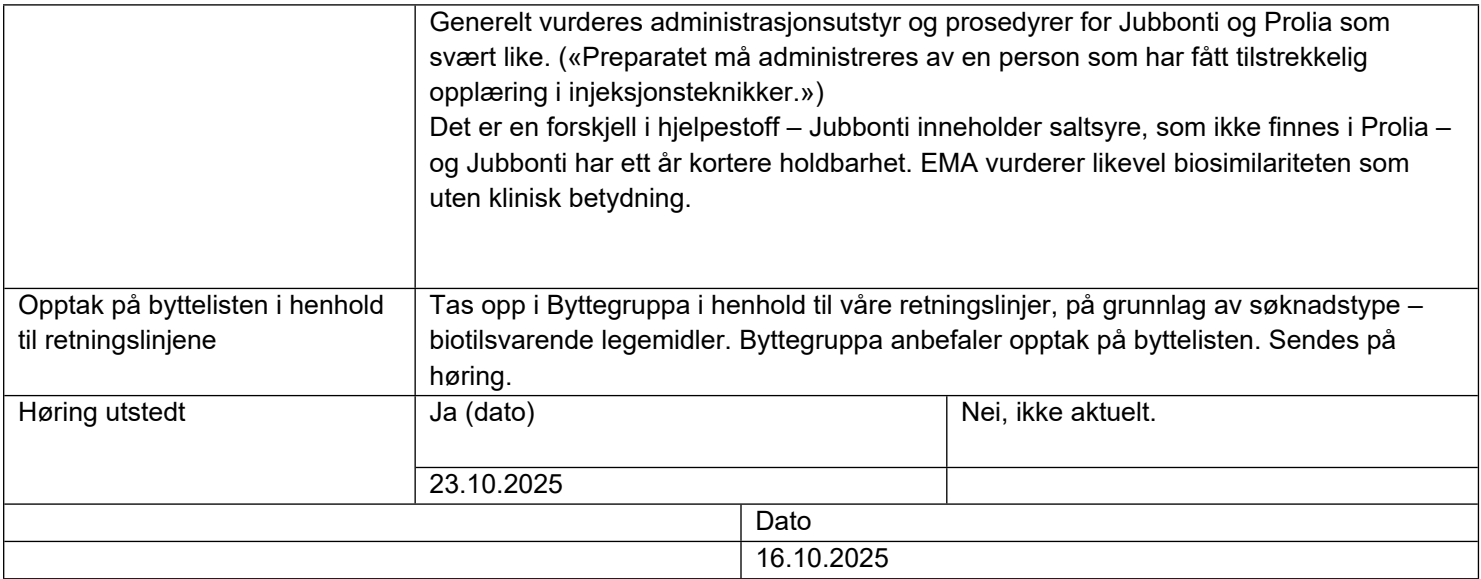




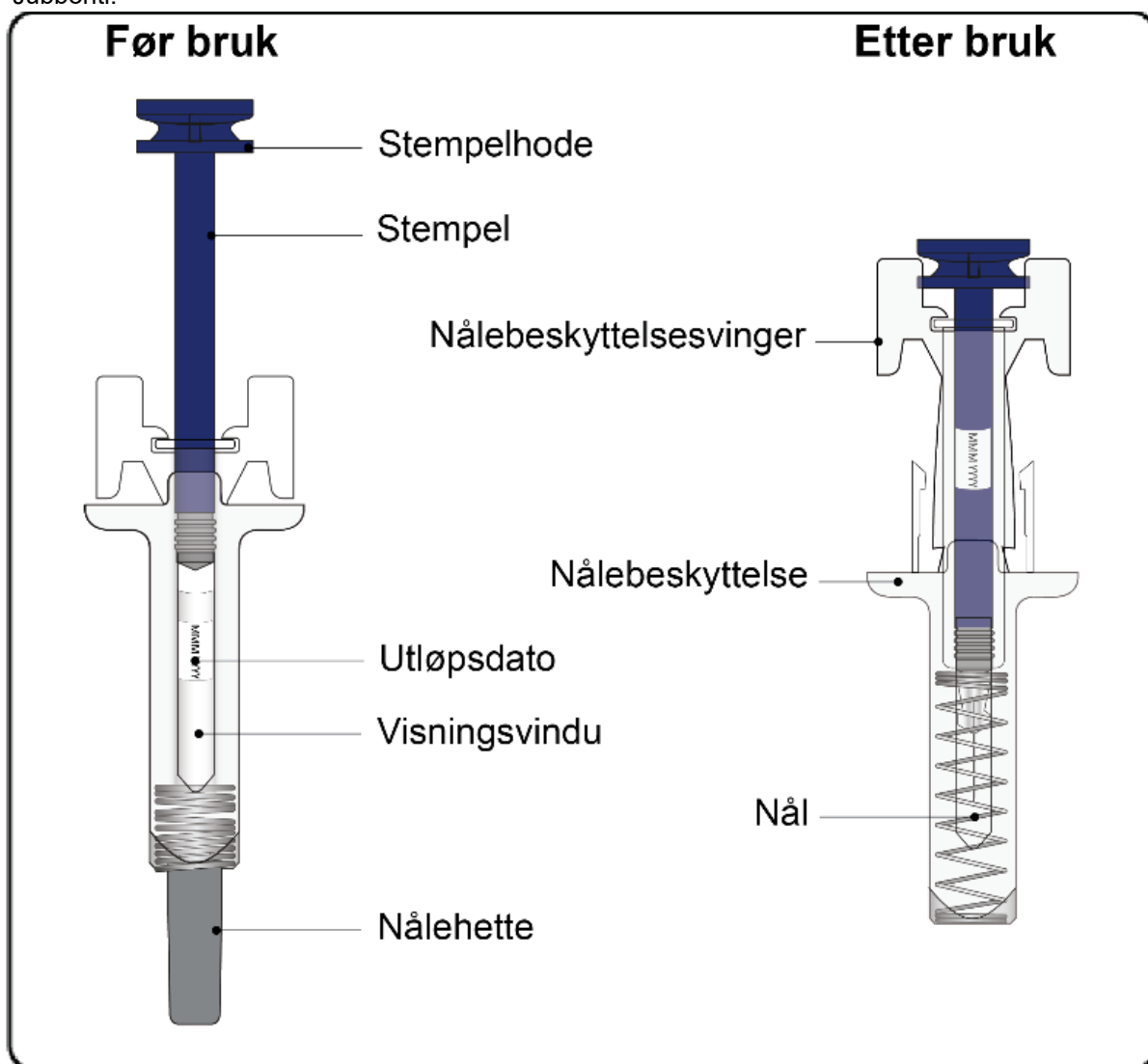
VURDERING AV BYTTBARHET

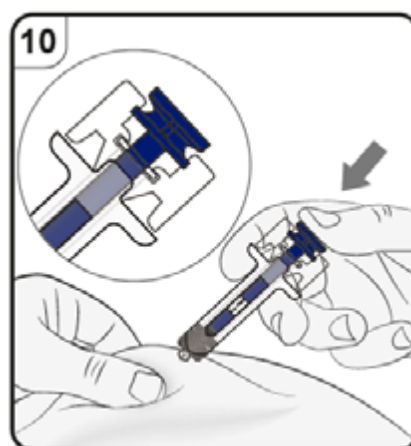
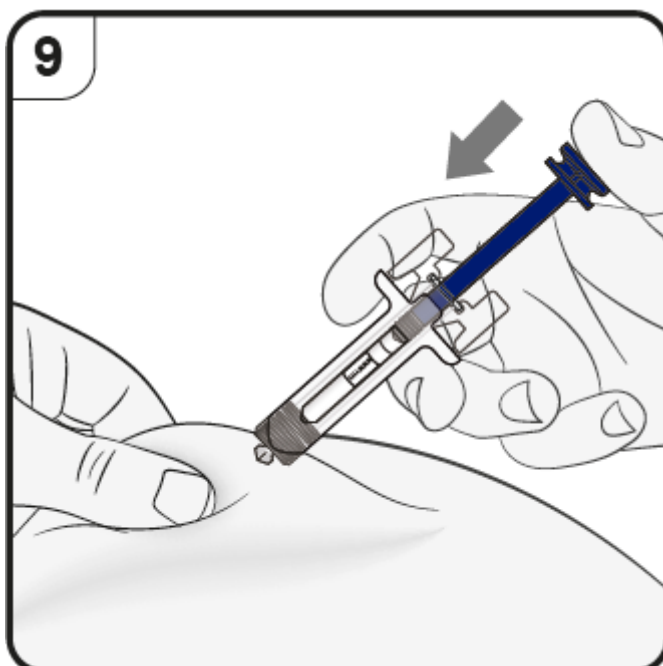
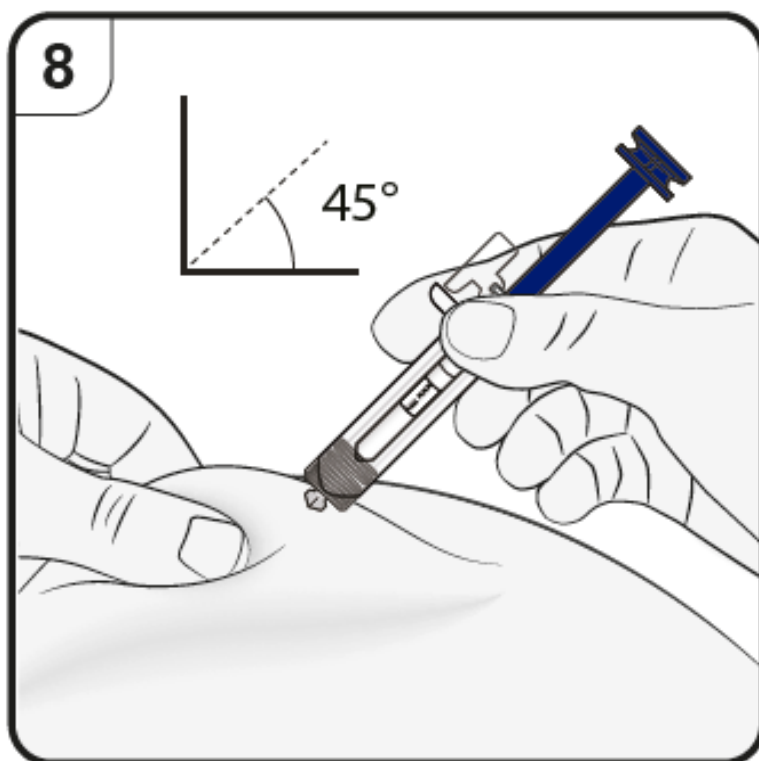
Tlf.: 22 89 77 00
Kto.: 7694 05 00903
Org.nr. 974 761 122

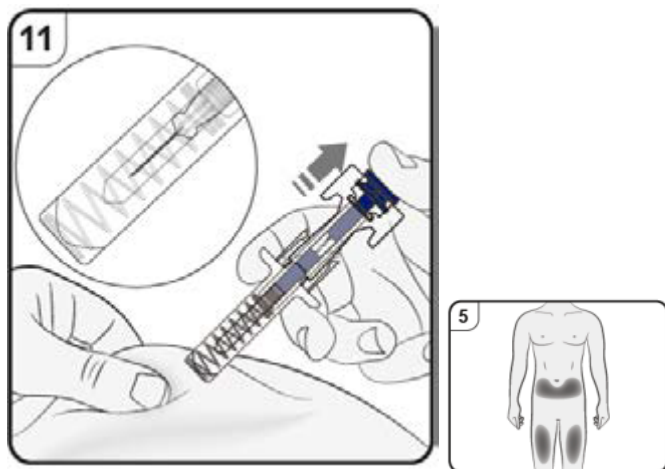
Vurdering i Assessment Report	Jubbonti (GP2411) was developed as a biosimilar product to Prolia (INN: denosumab), marketed by Amgen and was developed with the same strength and presentation: • Prolia: 60 mg/mL pre-filled syringe Overall conclusion The totality of the evidence as summarized in this dossier, including analytical, functional and clinical data, establishes biosimilarity of GP2411 to the reference product and supports extrapolation across indications. GP2411 and the reference product can be expected to produce the same clinical result in any given patient.
Vurdering av medisinsk likeverdighet	Jubbonti er godkjent i EU som biotilsvarende til Prolia. Iht. vedtak fra EMA er biotilsvarende legemidler som er godkjent i EU byttbare med referanseproduktet og med tilsvarende biotilsvarende produkter: statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines - EMA review following PROM endorsement (europa.eu) Jubonnti Jubbonti, INN-denosumab “The dose, frequency, and route of administration of the test and reference product were according to the SmPC of Prolia, which is considered acceptable.”



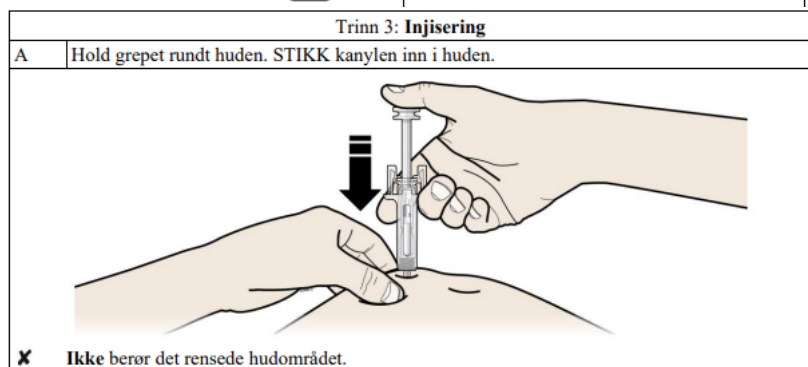
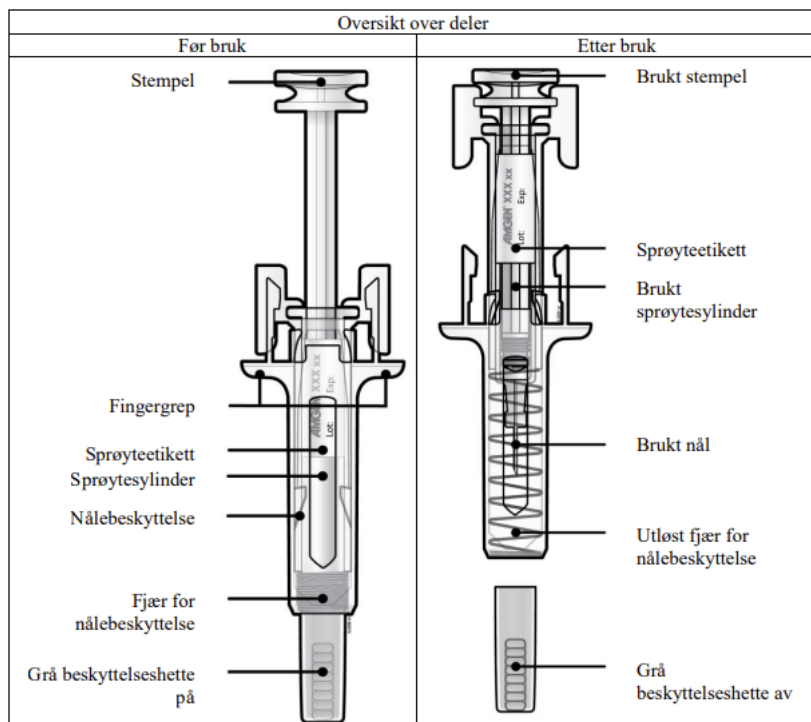
Jubbonti:



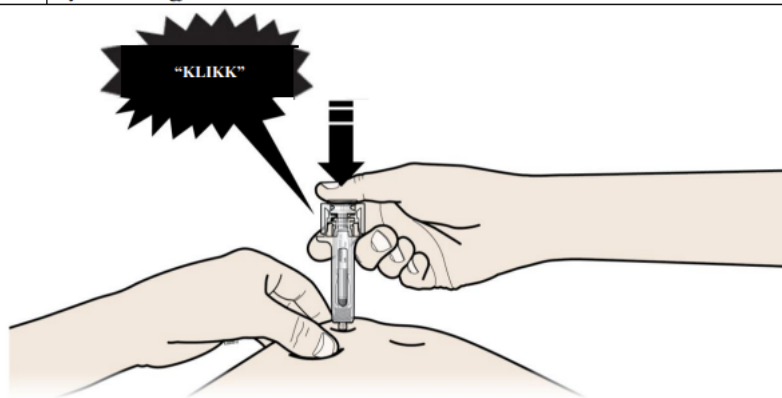




Prolia:

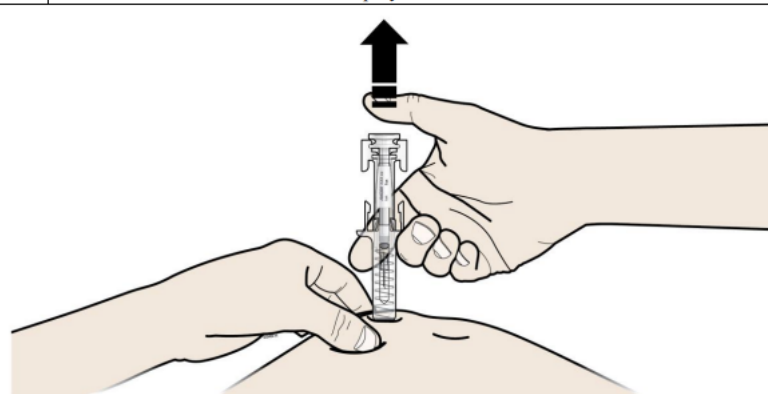


- B SKYV stempelet sakte inn med jevnt trykk til du kjenner eller hører et "klikk". Fortsett å skyve helt ned gjennom klikket.



! Det er viktig å skyve gjennom "klikket" for at hele dosen skal bli injisert.

- C SLIPP OPP tommelen. LØFT deretter sprøyten bort fra huden.



Etter at du har sluppet stempelet, vil nålebeskyttelsen i den ferdigfylte sprøyten dekke kanylen på en sikker måte.

✗ Ikke sett den grå beskyttelseshetten tilbake på brukte ferdigfylte sprøyter.

