

23 November 2018
EMA/822053/2018 rev3

Timetable of procedure

Referral under Article 30 of Directive 2001/83/EC

Septanest and associated names (articaine (hydrochloride)/ adrenaline (tartrate))

Procedure no: EMEA/H/A-30/1461

Procedural step:	Date:
Notification & dossier submission:	4-8 June 2018
Start of procedure (CHMP):	28 June 2018
Rapporteur / co-rapporteur assessment report(s) circulated to CHMP:	16 July 2018
Comments:	18 July 2018
Updated Rapporteur / co-rapporteur assessment reports circulated to CHMP:	20 July 2018
CHMP list of questions:	26 July 2018
Submission of responses:	24 October 2018
Re-start of the procedure:	29 October 2018
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	31 October 2018
Comments:	7 November 2018
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	9 November 2018

Procedural step:	Date:
CHMP list of outstanding issues:	November 2018 CHMP
Submission of responses:	7 February 2019
Re-start of the procedure	28 February 2019
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	8 March 2019
Comments:	15 March 2019
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	21 March 2019
CHMP list of outstanding issues/ CHMP opinion:	28 March 2019