

Annex I

List of medicinal products and presentations

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Septodont GmbH Felix-Wankel-Str. 9 D - 53859 Niederkassel-Mondorf Germany	Septanest mit Epinephrin 1:200.000	40 mg/ml + 0.005 mg/ml	Solution for injection	Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Austria	Septodont GmbH Felix-Wankel-Str. 9 D - 53859 Niederkassel-Mondorf Germany	Septanest mit Epinephrin 1:100.000	40 mg/ml + 0.01 mg/ml	Solution for injection	Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Belgium	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest Normal	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Belgium	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest Special	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Bulgaria	Laboratories Septodont 58, rue du Pont de Créteil 94107 Saint-Maur-des- Fossés Cedex France	Септанест с Адреналин 1/200 000	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Epinephrine 0.005 mg/ml

Bulgaria	Laboratories Septodont 58, rue du Pont de Créteil 94107 Saint-Maur-des- Fossés Cedex France	Септанест с Адреналин 1/100 000	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Epinephrine 0.01 mg/ml
Croatia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Croatia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Forte	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Cyprus	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Cyprus	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Forte	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml

Czech Republic	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanest s adrenalinem 1:200 000	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Czech Republic	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanest s adrenalinem 1:100 000	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Denmark	Spécialités Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Denmark	Spécialités Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septocaine	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Estonia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection in cartridge	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml

Estonia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Forte	40 mg/ml + 0.01 mg/ml	Solution for injection in cartridge	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Finland	Specialites Septodont. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septocaine	40 mg/ml + 5 microg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 5 microg/ml
Finland	Specialites Septodont. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septocaine Forte	40 mg/ml + 10 microg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 10 microg/ml
France	Septodont SAS 58, rue du Pont de Créteil 94107 Saint-Maur-Des- Fossés Cedex France	Septanest 40 mg/ml Adrenalinée au 1/200 000, solution injectable à usage dentaire	40 mg/ml + 0.005 mg/ml	Solution for injection	Local or regional injection intra-oral Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005mg/ml adrénaline (tartrate d') : non précisé

France	Septodont S.A.S. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Chlorhydrate d'Articaïne Septodont 40 mg/ml Adrénaline 1/200 000 , solution injectable	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use in the oral cavity	Articaïne hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml adrénaline (tartrate d') : non précisé
France	Septodont SAS 58, rue du Pont de Créteil 94107 Saint-Maur-Des- Fossés Cedex France	Septanest 40 mg/ml Adrenalinée au 1/100 000, solution injectable à usage dentaire	40 mg/ml + 0.01 mg/ml	Solution for injection	Local or regional injection intra-oral Submucosal use	Articaïne hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml adrénaline (tartrate d') : non précisé
France	Septodont S.A.S. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Chlorhydrate d'Articaïne Septodont 40 mg/ml Adrénaline 1/100 000, solution injectable	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use in the oral cavity	Articaïne hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml adrénaline (tartrate d') : non précisé
Germany	Septodont GmbH Felix-Wankel-Str. 9 D-53859 Niederkassel Germany	Septanest mit Epinephrin 1:200.000 - 40 mg/ml + 0,005 mg/ml Injektionslösung	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaïne hydrochloride 40 mg/ml Epinephrine 0.005 mg/ml

Germany	Septodont GmbH Felix-Wankel-Str. 9 D-53859 Niederkassel Germany	Septanest mit Adrenalin 1/200 000	40 mg/ml + 0.005 mg/ml	Solution for injection	Submucosal use	Articaine hydrochloride 40 mg/ml Epinephrine 0.005 mg/ml
Germany	Septodont GmbH Felix-Wankel-Str. 9 D-53859 Niederkassel Germany	Septanest mit Epinephrin 1:100.000 - 40 mg/ml + 0,01 mg/ml Injektionslösung	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Epinephrine 0.01 mg/ml
Germany	Septodont GmbH Felix-Wankel-Str. 9 D-53859 Niederkassel Germany	Septanest mit Adrenalin 1/100 000	40 mg/ml + 0.01 mg/ml	Solution for injection	Submucosal use	Articaine hydrochloride 40 mg/ml Epinephrine 0.01 mg/ml
Greece	John Tsaprazis SA 157 Michalakopoulou Str. 11527, Athens Greece	Septanest Ενέσιμο διάλυμα 4% + 1:200000	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration Periodontal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Greece	John Tsaprazis SA 157 Michalakopoulou Str. 11527, Athens Greece	Septanest Ενέσιμο διάλυμα 4% + 1:100000	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration Periodontal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Hungary	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.01 mg/ml	Solution for injection	Submucosal use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml

Italy	Spécialités Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection in cartridge	Infiltration	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Italy	Spécialités Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.01 mg/ml	Solution for injection in cartridge	Infiltration	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Latvia	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés Francija	Septanest 40 mg/5 mikrogrami/ml šķīdums injekcijām kārtidžā	40 mg/ml + 0.005 mg/ml	Solution for injection in cartridge	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Latvia	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés Francija	Septanest Forte 40 mg/10 mikrogrami/ml šķīdums injekcijām kārtidžā	40 mg/ml + 0.01 mg/ml	Solution for injection in cartridge	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Lithuania	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection in cartridge	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml

Lithuania	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Forte	40 mg/ml + 0.01 mg/ml	Solution for injection in cartridge	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Luxembourg	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest-N 1*200.000	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Luxembourg	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest Adrenaline 1:100.000	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Submucosal use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Malta	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest with adrenaline 1/200,000	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Malta	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest with adrenaline 1/100,000	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml

Netherlands	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest N	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Netherlands	Septodont Nv-Sa 87 Avenue de la Constitution B-1083 Brussel Belgium	Septanest SP	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Norway	Septodont 58, rue du Pont de Créteil 94107 Saint-Maur-Des- Fossés Cedex France	Septocaine	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Norway	Septodont 58, rue du Pont de Créteil 94107 Saint-Maur-Des- Fossés Cedex France	Septocaine Forte	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Poland	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Z Adrenalina 1: 200 000	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml

Poland	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Z Adrenalina 1: 100 000	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Portugal	Septodont S.A.S. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest 1/200 000	68 mg/1.7 ml + 0.015 mg/1.7 ml	Solução injetável	Via bucal	Articaina, cloridrato 40 mg/ml Adrenalina, tartarato 0.0091 mg/ml
Portugal	Septodont S.A.S. 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest 1/100 000	68 mg/1.7 ml + 0.031 mg/1.7 ml	Solução injetável	Via bucal	Articaina, cloridrato 40 mg/ml Adrenalina, tartarato 0.0182mg/ml
Romania	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Cu Adrenalină 1/200000	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Romania	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest Cu Adrenalină 1/100000	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml

Slovak Republic	Septodont 58, rue du Pont de Créteil, 94100 Saint-Maur-Des-Fossés, France	Septanest	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Slovak Republic	Septodont 58, rue du Pont de Créteil, 94100 Saint-Maur-Des-Fossés, France	Septanest Forte	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Slovenia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanestepi 40 mg/0,005 mg v 1 ml raztopina za injiciranje	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Slovenia	Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanestepi 40 mg/0,01 mg v 1 ml raztopina za injiciranje	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml
Spain	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des-Fossés France	Septanest con adrenalina 1/200.000	40 mg/ml + 0.005 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline bitartrate 0.005 mg/ml

Spain	Septodont 58 rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septanest con adrenalina 1/100.000	40 mg/ml + 0.01 mg/ml	Solution for injection	Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline bitartrate 0.01 mg/ml
Sweden	Specialites Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septocaine	40 mg/ml + 0.005 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.005 mg/ml
Sweden	Specialites Septodont 58, rue du Pont de Créteil 94100 Saint-Maur-des- Fossés France	Septocaine Forte	40 mg/ml + 0.01 mg/ml	Solution for injection	Dental use Infiltration and perineural use	Articaine hydrochloride 40 mg/ml Adrenaline 0.01 mg/ml