

Recommendations of the SEC (Dentistry) made in its 01st/24 meeting held on 20.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/23/000041 Endomethasone N	M/s. Septodont Healthcare India Pvt.Ltd.	<p>Firm presented the application of grant of regularization NCO to import of drug ENDOMETHASONE N along with data on the clinical trial and safety study of drug ENDOMETHASONE N.</p> <p>The firm presented one published clinical study data and regulatory status of the drug ENDOMETHASONE before the experts.</p> <p>After detailed deliberation, the subject expert committee opined that the data of clinical trial presented by the firm is not sufficient to prove the safety of the drug ENDOMETHASONE.</p> <p>Further, the subject expert committee informed that the recent literature¹ showed that the use of the preparation containing ENDOMETHASONE drug showed cytotoxic effect.</p> <p>In view of the above, the subject expert committee recommended that the firm should provide a robust comparative data spanning at least the last five years as well as submit more scientific evidences/literature on clinical trial and safety data on safe use of drug ENDOMETHASONE N before the committee for further consideration</p> <p>Literature Reference: -</p> <p>Cytotoxicity and release ions of endodontic sealers incorporated with a silver and vanadium base nanomaterial, Ana Beatriz Vilela Teixeira, Denise Tornavoi de Castro, Marco Antônio Schiavon, Andréa Cândido dos Reis, Springer, 21-March-2020).</p> <p>Colak, K. M., Keles, A., Bayrak, O. F., Koseoglu, M., & Sahin, F. (2009). Study of cytotoxicity of six root canal sealing dental materials. <i>Materials Research Innovations</i>, 13(4), 415–420. https://doi.org/10.1179/143289109X12494867167161 (The toxicity response decreased</p>

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			<p>in the order of AH 26>Sealapex>Diaket>Endomethasone>AH Plus>RSA. These results confirm that the dilute solution of root canal sealers after being set for extended period of times caused moderate or severe toxic reactions to culture cells.)</p> <p>Schwarze T, Leyhausen G, Geurtsen W. Long-term cytocompatibility of various endodontic sealers using a new root canal model. J Endod. 2002 Nov;28(11):749-53. doi: 10.1097/00004770-200211000-00001. PMID: 12470017. (Furthermore, statistically significant cytotoxic alterations were also induced by 10-week eluates of Endomethasone (p < 0.05).)</p> <p>Badole GP, Warhadpande MM, Meshram GK, Bahadure RN, Tawani SG, Tawani G, Badole SG. A comparative evaluation of cytotoxicity of root canal sealers: an in vitro study. Restor Dent Endod. 2013 Nov;38(4):204-9. doi: 10.5395/rde.2013.38.4.204. Epub 2013 Nov 12. PMID: 24303354; PMCID: PMC3843030. (Endomethasone N was showed mild toxicity in all periods of time.)</p> <p>Rahman, Hena*; Chandra, Anil**; Tikku, A P**; Konwar, Rituraj***; Verma, Promila****; Yadav, R K*****. Comparative evaluation of cytotoxicity profile of different root canal sealers - in vitro. Endodontology 24(1):p 42-47, Jan–Jun 2012. DOI: 10.4103/0970-7212.352066 (The study concluded that Endomethasone N exhibit highest toxic towards cultured cells. EndoREZ and Acroseal were comparatively less toxic whereas RoekoSEAL and AH-Plus showed intermediate cytotoxicity.)</p> <p>Hegde, Mithra N*; Rodrigues, Jean C**; Kumari, Suchetha***; Hegde, Nidarsh D****. Toxicity evaluation of root canal sealers on human gingival fibroblasts. Endodontology 23(1):p 42-48, Jan–Jun 2011. DOI: 10.4103/0970-7212.352014 (All sealers showed a varied amount of</p>

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			<p>cytotoxic response from lowest toxicity to highest toxicity in the increasing order i.e. Pulpdent Root Canal Sealer <Endomethasone< AH 26. All the sealers were initially toxic at the 24thhour and the toxicity decreased over time as the sealers set.)</p> <p>Jeanneau C, Giraud T, Milan JL, About I. Investigating unset endodontic sealers' eugenol and hydrocortisone roles in modulating the initial steps of inflammation. Clin Oral Investig. 2020 Feb;24(2):639-647. doi: 10.1007/s00784-019-02957-2.</p> <p>Guedes Pinto T, Claudia Muniz Renno A, Nunes Dos Santos J, Ramos Cury P, Araki Ribeiro D. Genotoxicity induced by endodontic sealers: A systematic review. Saudi Dent J. 2024 Feb;36(2):249-257.</p>