



Safeguarding public health

**Defective Medicines Report Centre
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**DRUG ALERT
CLASS 2 MEDICINES RECALL**

**Action Within 48 Hours
PATIENT AND PHARMACY OR EQUIVALENT LEVEL RECALL**

Date: 16 December 2009

EL (09)A/34

Our Ref: MDR 24-12/09

Dear Healthcare Professional,

DDD Limited

Dentinox Teething Gel

PL 00133/5010R

**(Cetylpyridium Chloride and Lidocaine
Hydrochloride Teething Gel)**

Batch Number	Expiry Date	Pack Size	First Distributed
BASEP09	SEP 2012	15G	28 OCTOBER 2009
BBSEP09	SEP 2012	15G	06 OCTOBER 2009
BGSEP09	SEP 2012	15G	26 OCTOBER 2009
BLSEP09	SEP 2012	15G	16 NOVEMBER 2009
BFOCT09	OCT 2012	15G	13 NOVEMBER 2009
BFNOV09	NOV 2012	15G	24 NOVEMBER 2009
BINOV09	NOV 2012	15G	19 NOVEMBER 2009
BGNOV09	NOV 2012	15G	26 NOVEMBER 2009

DDD Limited is recalling the above batches of Dentinox Teething Gel due to the presence of very small amounts of a contaminant, Glyoxal, in the product.

Glyoxal occurs naturally and is found in the environment and some foods at very low levels. Affected batches are being recalled as a precaution due to the possibility of accumulation since the product is used in infants and young children with immature metabolic systems. The Company has not received any reports of adverse reactions associated with these batches.

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency
Market Towers 1 Nine Elms Lane London SW8 5NQ
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

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For Medical Information enquiries, please call DDD Limited's Consumer Careline on 0208 9949874

Consumers are being asked to return the affected teething products to the retailers from whom they bought the goods. In addition to consumer returns, pharmacists are asked to remove the Teething Gel from their shelves.

If Dentinox Teething Gel has previously been purchased directly from Dendron then please retain this stock and your Dendron Territory Manager will uplift this from you upon his or her next scheduled call. If the product has been purchased from your Chemist Wholesaler, then please return this stock directly to the Wholesaler. For further queries relating to stock return please contact 01923 205704

As this product is a GSL medicine, the Agency has expanded the scope of this recall to include patient level notification. This notification will be supported by press notifications by the marketing authorisation holder and the MHRA.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this to relevant clinics and to General Practitioners and Community Pharmacists for information. Wholesalers are requested to ensure that this information is forwarded to all GSL customers.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC