



Medicines & Healthcare products
Regulatory Agency



Oral Lidocaine-containing products for teething in children

Quick reference guide

In December 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) issued new advice for the use of oral lidocaine-containing products for teething in children. Oral lidocaine products authorised for teething are becoming Pharmacy medicines and additional measures will be introduced. This quick reference guide provides information on the recommendations, the background to why these changes have been introduced, the affected products and advice to support you when you have conversations with parents or carers.

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Background information

The Medicines and Healthcare products Regulatory Agency (MHRA) reviewed the benefits and risks of oral lidocaine products, taking into account all the available evidence.

The MHRA review was passed to the Commission on Human Medicines (CHM; an independent body who gives advice to UK government Ministers about the safety, quality, and efficacy of medicines) for advice.

The CHM advised on measures to improve the safe use of oral lidocaine-containing products for teething in children. The CHM identified a number of reports of medication error received via the Yellow Card Scheme (see Public Assessment Report). Most reports did not include an associated adverse event and were not thought to result in harm, but the committee recommended that the administration instructions should be improved and harmonised to ensure parents and caregivers received consistent advice on the safe use of these medicines in children.

The CHM recommended that pharmacists were best placed to provide guidance to parents and caregivers on options for teething symptoms, including when symptoms could suggest more serious conditions that need medical assessment.

The CHM advised the following new risk minimisation measures to improve the balance of risks and benefits for these medicines:

- Change of legal status of newly manufactured stock of oral lidocaine-containing products from general sale (GSL) to pharmacy (P).
- Update and harmonisation of posology and safety warnings across all oral lidocaine products authorised for teething.
- Restriction of the pack size of oral lidocaine products authorised for teething to a maximum of 10 grams.
- Re-positioning of oral lidocaine products as second-line, after non-pharmacological treatments.
- Update to oral, over the counter, lidocaine products licensed in children for other indications, and oral lidocaine products licensed in adults, to carry a warning against use in teething.

In December 2018, the MHRA announced the comprehensive package of measures set out in the advice from the CHM. The Drug Safety Update article is available on the MHRA website:

<https://www.gov.uk/drug-safety-update/oral-lidocaine-containing-products-for-infant-teething-only-to-be-available-under-the-supervision-of-a-pharmacist>

Guidance

Which lidocaine-containing products were considered in the review?

The following table provides the list of lidocaine-containing products that were considered in the review:

Product name	Lidocaine % (w/w)	Product Licence Number
Lidocaine-containing products authorised for teething		
Anbesol® Teething Gel	1.00%	PL 16853/0126
Anbesol® Liquid	0.90%	PL 16853/0128
Bonjela® Teething Gel	0.33%	PL 00063/0048
Bonjela® Junior Gel	0.50%	PL 00063/0657
Boots® Teething Gel 3 Months+	0.60%	PL 00014/0392
Calgel® Teething Gel	0.33%	PL 15513/0015
Dentinox® Teething Gel	0.33%	PL 00133/5010R
Lidocaine-containing products authorised in adults or for other indications		
Anbesol® Adult Strength Gel	2.00%	PL 16853/0127
Boots® Mouth Ulcer Gel	0.60%	PL 00014/0150
Iglu® Gel	0.66%	PL 00173/0186
Iglu® Rapid Relief Gel	0.66%	PL 00173/0406
Medijel® Gel	0.66%	PL 00133/5000R

What are the changes that pharmacy teams need to explain to parents/carers?

Lidocaine-containing products authorised for teething will no longer be available as GSL but will be P medicines that are supplied from pharmacies, by or under supervision of a pharmacist. There are new instructions on how to use the products and new advice that they should be used as second-line, after non-pharmacological treatments. Parents/carers are encouraged to read the updated patient information leaflet to be familiar with the new advice. The pack size and packaging of the products will also appear different because the pack size of the products is restricted to a smaller quantity of 10 grams.

Lidocaine-containing products authorised in adults or for other indications (e.g. mouth ulcers) will be clearly labelled with a warning: 'Not suitable for treatment of teething in children'.

Parents/carers asking why have these changes been introduced?

A group of medicines experts called the Commission on Human Medicines has reviewed these products. They considered evidence for the benefit and risks of the medicines and made recommendations to make their use safer.

The experts recommended that pharmacists are best placed to advise parents and caregivers of when and how lidocaine teething medicines should be used. This means the medicines will be available from pharmacies on the advice of a pharmacist and soon will no longer be available from other shops or supermarkets.

Advise parents/carers that more information is available from the MHRA parent/carer guide that can be downloaded from:

<https://assets.publishing.service.gov.uk/media/5c0fd7cbcd915d0c736a1e64/Lidocaine-patient-sheet.pdf>

What treatment/advice can be provided for teething?

Teething is a normal process. Simple, self-care measures are recommended by the current National Institute for health and Care Excellence (NICE) summary for Teething, as first steps for relief of associated discomfort. These include gentle rubbing of the gum with a clean finger and allowing the child to bite on a clean and cool object.

Paracetamol or ibuprofen suspension, administered according to the approved indication and dose, can be considered for infants 3 months of age or older if required. If the child is unwell or the symptoms do not improve, parents or carers should consider talking to a healthcare professional. Oral lidocaine products that are approved in adults or in other conditions should not be used.

How to use lidocaine-containing teething gels?

Advise parents or carers to follow very closely the directions on the updated patient information leaflet. This will give details of how much to apply and how often which are very important to follow to avoid potential side effects.

The harmonised posology for lidocaine-containing teething gels is:

Apply a pea sized blob of gel (see circle shown in the patient information leaflet) to a clean fingertip and spread gently onto the sore area of the gum. If necessary, repeat the dose after 3 hours. Do not use more than 6 times in one day (24 hour period).

Parents/carers asking I am concerned that we have used lidocaine products on my child should I be worried?

If you have given the dose as recommended on the product, you do not need to worry. However, if you have concerns about the health of your baby, you should contact a healthcare professional. If you think an overdose has occurred, you should stop using the lidocaine products and seek the advice of a healthcare professional.

Is there any change to lidocaine-containing products authorised for other indications (e.g. mouth ulcers) or in adults?

The legal status of these products has not changed but they will be clearly labelled with a warning: 'Not suitable for treatment of teething in children'. They can continue to be administered according to the approved indication and dosing regimen and following product instructions.

Parents and carers are advised not to use these products for treatment of teething.

What are the timelines for the change-over to newly packaged products?

Updated oral lidocaine-containing products will be available in pharmacies from the beginning of 2019. Products with older packaging are no longer being manufactured. The remaining GSL products will not be withdrawn but we are asking pharmacies and retailers to make these available only on the advice of a pharmacist.

Pharmacy teams can bring back the older GSL stock behind the counter to subsequently supply them with counselling on the new administration instructions. Advise parents and carers that old packaging and product leaflets will not reflect the new harmonised posology and safety warnings and pharmacists could provide parents and caregivers with the most up-to-date instructions (provided in the Patient Information Leaflets on EMC).

Where to find more information on the new recommendations?

Healthcare professionals can read about the evidence that was considered from:

- MHRA Public Assessment Report:
https://assets.publishing.service.gov.uk/media/5c0fded9ed915d0bbf782c2d/Lidocaine_PAR-for-pub.pdf
- Drug Safety Update article:
<https://www.gov.uk/drug-safety-update/oral-lidocaine-containing-products-for-infant-teething-only-to-be-available-under-the-supervision-of-a-pharmacist>

For parents and carers, a guide is available and can be downloaded from:

<https://assets.publishing.service.gov.uk/media/5c0fd7cbcd915d0c736a1e64/Lidocaine-patient-sheet.pdf>