



## Materia Medica Maibach

### IMPORTANT MESSAGE

#### **40188 Ultracain® D-S forte, Solution for injection (articaine / adrenaline) Medicinal Product Information Update**

31 January 2024

Dear Doctor,

In agreement with Swissmedic, as the Marketing Authorisation Holder of Ultracain® D-S forte, solution for injection for infiltration and block anesthesia, Materia Medica Maibach AG would like to inform you of the following:

#### **Summary**

- **Packs of Ultracain® D-S forte distributed on the Swiss market do not contain the most recently approved medicinal product information.**  
The packs contain the medicinal product information with the date of revision of the text «February 2014» instead of the most recently approved medicinal product information with the date of revision of the text «September 2022». As a result, the Information for Healthcare Professionals enclosed with the pack does not contain the most up-to-date information.
- **The batch affected is Ultracain® D-S forte 3F259A, EXP 12/2025.**

#### **Background information**

Following a procedure to harmonize the SmPC of products containing articaine and adrenaline in the European Union, the Swiss Information for Healthcare Professionals of Ultracain® D-S/D-S forte was also updated and approved by Swissmedic with respect to the following sections: «Indications/Uses», «Dosage/Administration», «Contraindications», «Warnings and precautions», «Interactions», «Pregnancy, lactation», «Undesirable effects», and «Overdose». The comparison between the previous and the current versions of the Information for Healthcare Professionals showed no impact on the favorable benefit/risk ratio of this well-established product.

#### **Recommendation**

We recommend that dentists access the up-to-date product information of Ultracain® D-S/D-S forte directly on [www.swiss-medinfo.ch](http://www.swiss-medinfo.ch).

#### **Adverse drug reaction reporting**

For reporting adverse drug reactions (ADRs), Swissmedic recommends using the Electronic Vigilance System (EViS) portal developed for this purpose. All the necessary information can be found at [www.swissmedic.ch](http://www.swissmedic.ch)

#### **Contact**

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Kind regards

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