<DATE>

Neofordex 40 mg (dexamethasone): removal of the score-line and the associated 20 mg posology

Dear Healthcare professional,

Laboratoires CTRS in agreement with the European Medicines Agency (EMA) and the <National Competent Authority> would like to inform you of the following:

Summary

- **The score line on Neofordex (dexamethasone) 40 mg tablets has been removed.**
- **Neofordex tablet should only be given at the 40 mg posology. For patients where a 20 mg dose is needed, another dexamethasone product should be prescribed.**
- **Patients should be advised not to cut tablets, and to store the tablets in original blisters until administration.**
- **The tablets have been changed to a non-scorable tablet, with a 40 mg imprint on one side. The product information and the packaging have been updated accordingly.**

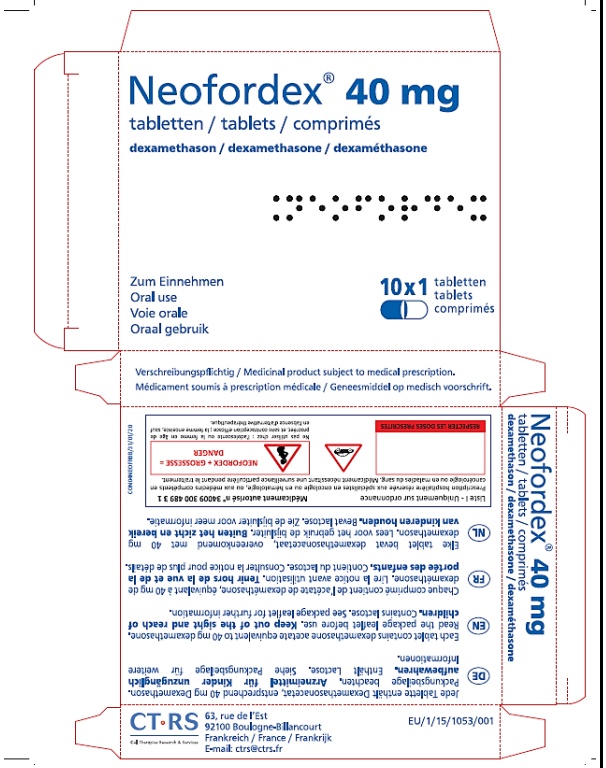
Background on the safety concern

Neofordex is indicated in adults for the treatment of symptomatic multiple myeloma in combination with other medicinal products. The usual posology of dexamethasone is 40 mg once daily. For elderly and/or frail patients, or in situations where it is required by the therapeutic protocol, the daily dexamethasone dose may be reduced to 20 mg. In addition, at the end of dexamethasone treatment, the dose should be tapered in a stepwise fashion until a complete stop.

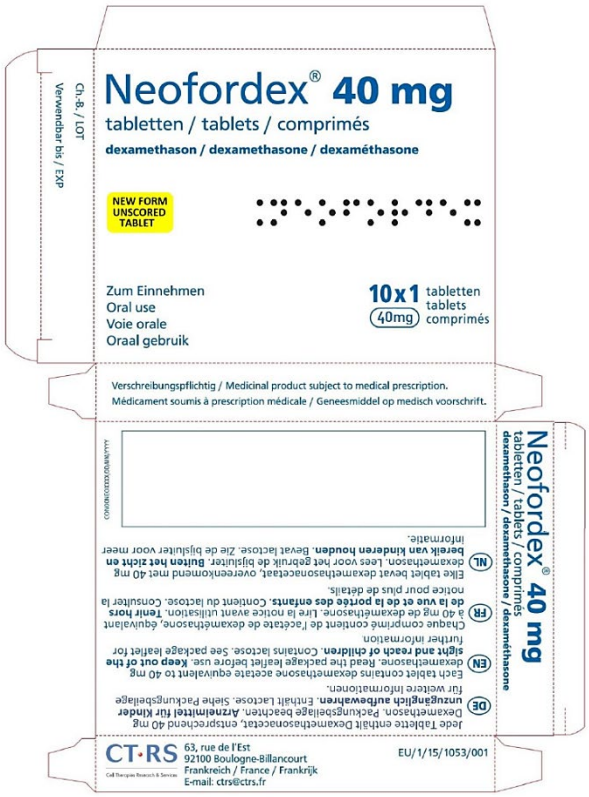
Due to the risk of reduced stability (due to sensitivity to humidity) and reduction of efficacy if a halved tablet is not used immediately, the score line has been removed and It is therefore not possible to split the tablet into equal halves anymore. The new Neofordex tablet will only allow administration of 40 mg. In patient groups where the dexamethasone dose needs to be reduced to 20 mg, the treating physicians should prescribe other products containing a lower dose of dexamethasone. Patients should be informed and specifically advised not to cut tablets, and to store the tablets in original blisters until administration.

The product information (SmPC and package leaflet) has been revised to reflect the changes related to removal of the score line and the consequent deletion of the 20 mg posology. The outer carton of the product has also been updated, to change the picture of the scorable tablet into an entire, non-scorable tablet. A 40 mg imprint has been added on one side of Neofordex tablets. Qualitative and quantitative composition remain unchanged.

Current outer packaging

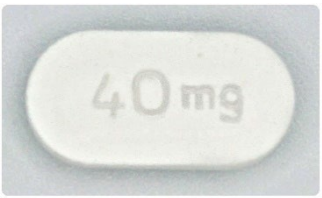


New outer packaging



Current tablets (with score-line)

New tablets (without score-lines)



Transition period between the two forms (with and without score-line is planned as per below table:

	Last batch with score-line on the market	**First batch without score-line on the market**
France	Expiry date: 31/10/2023 Anticipated end date of distribution: 04/2023	Planned commercialisation date: 04/2023 Expiry date: 28/02/2024
NORDICS (Denmark, Norway, Sweden)	Expiry date: 31/10/2023 Anticipated end date of distribution: 10/2022	Planned commercialisation date: 02/2023 Expiry date: 04/2025
Greece	Expiry date: 31/10/2023 Anticipated end date of distribution: 01/2023	Planned commercialisation date: 02/2023 Expiry date: 04/2025

Call for reporting

Any product defects or adverse events occurring in patients receiving Neofordex should be reported to *(market specific AE statement*). Please remember to provide details of the product name and batch number when reporting.

Company contact point

For further information, **please contact xxxx** [add national contact details]

Communication plan for Direct healthcare professional communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Neofordex, 40 mg tablets (dexamethasone)
Marketing authorisation holder(s)	Laboratoires CTRS
Safety concern and purpose of the communication	The purpose of this communication is to notify HCPs of the score line removal on Neofordex's tablets and the associated 20mg posology in the SmPC and leaflet.
DHPC recipients	Prescribing physicians including hematologists, oncologists; pharmacists The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	In all EEA member states where Neofordex is on the market.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	10 June 2022
DHPC and communication plan (in English) agreed by CHMP	23 June 2022
Submission of translated DHPCs to the national competent authorities for review	1 July 2022
Agreement of translations by national competent authorities	8 July 2022
Dissemination of DHPC	Shortly ahead of the launch of the product (without score-line) in the respective MS