# Emselex

## Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
|---|---|---|---|---|---|
| PSUR / EMA/PSUR/0000248469 | In view of available data on risk(s) from the | 19/06/2025 | | SmPC and PL | Based on the PRAC review of data on safety and |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

| | | | | | |
|---|---|---|---|---|---|
| | literature, spontaneous reports including in 8 cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between darifenacin and confusional state is at least a reasonable possibility. In view of available data on risk(s) from the literature, spontaneous reports including 2 cases with positive de-challenge, positive rechallenge and compatible TTO, 5 cases with a compatible TTO and positive de-challenge and other 13 cases with a close temporal association, the PRAC considers a causal relationship between darifenacin, and muscle spasm is at least a reasonable possibility. The PRAC concluded that the product information of products containing darifenacin should be amended accordingly. | | | | efficacy, the PRAC considers that the benefit-risk balance of medicinal products containing darifenacin remains unchanged but recommends that the terms of the marketing authorisation(s) should be varied as follows: Update of section 4.8 of the SmPC to add the adverse reactions confusional state and muscle spasms with a frequency not known. The Package leaflet is updated accordingly. • Dementia should be closely monitored in the next PSURs. Relevant publications about darifenacin and other antimuscarinic drugs used to OAB should be presented in the next PSUR, as well as the articles about additive effects of different anticholinergic drugs along with darifenacin or other antimuscarinic drugs used to OAB. Cases of dementia with darifenacin should be cumulatively review in the next PSUR with detailed information about the concomitant medications. • Diabetes mellitus (new onset or impairment of pre-existing DM)' should continue to be close monitored as important potential risk. • Muscular weakness and myalgia should continue to be monitored through the PSURs. The current frequency of submission should be changed from 3 years to 5 years at the first possibility. The list of Union reference dates (EURD) should be updated accordingly. |
| Variation type IB / EMA/VR/0000235712 | This was an application for a group of variations.<br><br>B.II.b.1 Replacement or addition of a | 17/12/2024 | | Annex II and PL | |

| | | | | | |
|---|---|---|---|---|---|
| | manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted<br><br>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.b Primary packaging site - Accepted<br><br>B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.2 Including batch control/testing - Accepted<br><br>B.II.a.3.a Changes in components of the flavouring or colouring system - B.II.a.3.a.1 Addition , deletion or replacement - Accepted<br><br>B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.b Downscale of the batch size down to 10-fold for the pharmaceutical form medicinal gas - Accepted<br><br>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted<br><br>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted<br><br>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted<br><br>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted<br><br>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted<br><br>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted<br><br>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted<br><br>B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted<br><br>B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - Accepted | | | | |