# Tavlesse

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification[1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| R/0018 | Renewal of the marketing authorisation. | 19/09/2024 | 13/11/2024 | SmPC, Annex II, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Tavlesse in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.<br>Pursuant to Article 23(3) of Regulation No (EU) 726/2004, |

[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).

| | | | | | |
|---|---|---|---|---|---|
| | | | | | Tavlesse (Fostamatinib) is removed from the additional monitoring list as a new active substance following five years of authorisation. Therefore, the statement that this medicinal product is subject to additional monitoring and that this will allow quick identification of new safety information, preceded by an inverted equilateral black triangle, is removed from the summary of product characteristics and the package leaflet. |
| PSUSA/10819 /202404 | Periodic Safety Update EU Single assessment - fostamatinib | 31/10/2024 | n/a | | PRAC Recommendation - maintenance |
| IB/0019 | B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation | 17/06/2024 | n/a | | |
| PSUSA/10819 /202304 | Periodic Safety Update EU Single assessment - fostamatinib | 30/11/2023 | n/a | | PRAC Recommendation - maintenance |
| IB/0016 | B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | 20/11/2023 | n/a | | |
| PSUSA/10819 /202204 | Periodic Safety Update EU Single assessment - fostamatinib | 01/12/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0014 | B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) | 09/09/2022 | 22/09/2023 | SmPC | |
| IB/0012 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 12/08/2022 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| PSUSA/10819 /202110 | Periodic Safety Update EU Single assessment - fostamatinib | 10/06/2022 | n/a | | PRAC Recommendation - maintenance |
| N/0010 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 10/01/2022 | 22/09/2023 | PL | |
| PSUSA/10819 /202104 | Periodic Safety Update EU Single assessment - fostamatinib | 02/12/2021 | n/a | | PRAC Recommendation - maintenance |
| IB/0009 | B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation | 24/08/2021 | n/a | | |
| PSUSA/10819 /202010 | Periodic Safety Update EU Single assessment - fostamatinib | 24/06/2021 | 18/08/2021 | SmPC and PL | Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10819/202010. |
| IB/0006/G | This was an application for a group of variations.<br><br>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method<br>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method<br>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its | 08/03/2021 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| | corresponding test method<br>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method<br>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method | | | | |
| PSUSA/10819 /202004 | Periodic Safety Update EU Single assessment - fostamatinib | 29/10/2020 | n/a | | PRAC Recommendation - maintenance |
| N/0005 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 23/09/2020 | n/a | | |
| IAIN/0003/G | This was an application for a group of variations.<br><br>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site<br>B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing | 22/06/2020 | 17/06/2021 | Annex II and PL | |
| T/0002 | Transfer of Marketing Authorisation | 12/03/2020 | 01/04/2020 | SmPC, Labelling and | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | PL | |