**ПЕРЕЛІК**

**ЛІКАРСЬКИХ ЗАСОБІВ ЩОДО ЯКИХ ЗАВЕРШЕНО РОЗГЛЯД РЕЄСТРАЦІЙНИХ МАТЕРІАЛІВ ПРО ВНЕСЕННЯ ЗМІН ДО РЕЄСТРАЦІЙНИХ МАТЕРІАЛІВ ПРОТЯГОМ ДІЇ РЕЄСТРАЦІЙНОГО ПОСВІДЧЕННЯ НА ЛІКАРСЬКІ ЗАСОБИ, ЯКІ ЗАРЕЄСТРОВАНІ КОМПЕТЕНТНИМИ ОРГАНАМИ СПОЛУЧЕНИХ ШТАТІВ АМЕРИКИ, ШВЕЙЦАРСЬКОЇ КОНФЕДЕРАЦІЇ, ЯПОНІЇ, АВСТРАЛІЇ, КАНАДИ, ЛІКАРСЬКИХ ЗАСОБІВ, ЩО ЗА ЦЕНТРАЛІЗОВАНОЮ ПРОЦЕДУРОЮ ЗАРЕЄСТРОВАНІ КОМПЕТЕНТНИМ ОРГАНОМ ЄВРОПЕЙСЬКОГО СОЮЗУ**

| ***№ п/п*** | ***Назва лікарського засобу*** | ***Форма випуску (лікарська форма, упаковка)*** | ***Заявник*** | ***Країна*** | ***Виробник*** | ***Країна*** | ***Реєстраційна процедура*** | ***Умови відпуску*** | ***Номер реєстраційного посвідчення*** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **КЕНГРЕКСАЛ** | порошок для концентрату для розчину для ін'єкцій / інфузій, 50 мг; 10 флаконів з порошком у флаконі в картонній коробці з маркуванням італійською, німецькою та англійською мовами зі стікером українською мовою | К'єзі Фармас'ютікелз ГмбХ | Австрія | виробництво, контроль якості та первинне пакування: Патеон Італія С.п.А., Італiя; вторинне пакування: К'єзі Фармацеутиці С.п.А., Італія; випуск серії: Хальса Фарма ГмбХ, Німеччина | Італія/Німеччина | внесення змін до реєстраційних матеріалів: C.I.3.z, IB - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation: To update SmPC sections 4.2, 5.1 and 5.2 with data on the posology in paedeatric patients, following the outcome of EMEA/H/C/003773/P46/003.1. Введення змін - протягом 6-ти місяців після затвердження. | *за рецептом* | UA/17224/01/01 |
|  | **ЛАНСУРФ® 15 МГ/6,14 МГ** | таблетки, вкриті плівковою оболонкою, по 15 мг/6,14 мг, по 10 таблеток у блістері; по 2 або 6 блістерів у коробці з картону | Лє Лаборатуар Серв'є | Францiя | відповідальний за виробництво, контроль якості та випуск серії продукції in bulk:Тайхо Фармасьютікал Ко., Лтд., Японiя;відповідальний за контроль якості, первинне та вторинне пакування і випуск серії готового лікарського засобу:Лабораторії Серв'є Індастрі, Францiя | Японія/Франція | внесення змін до реєстраційних матеріалів: A.7, IA - Administrative change - Deletion of manufacturing sites: To delete sites not involved in routine manufacturing and testing of the active substance trifluridine, namely Laboratories or Facilities for Analytical Method Development (section 3.2.S.2.1.4), Laboratories or Facilities for Analytical Method Validation (section 3.2.S.2.1.5), and Laboratories or Facilities for Stability Study (section 3.2.S.2.1.6). In addition, the MAH and the ASMFH have taken the opportunity to introduce editorial changes as listed in the present / proposed table of the respective summary documents. B.I.d.1.a.4, IB - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data: To extend the re-test period of the active substance trifluridine from 36 months to 48 months with no special storage. B.I.b.2.e, IB- Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate: To replace the GC (method A) test procedure with revised GC method for the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), methanol, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), ethanol, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), acetone, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), isopropyl ether, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), chloroform, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method B), pyridine, from the specifications of the active substance trifluridine. B.III.2.a.1, IAin - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State – AS: To change the specification for the active substance trifluridine to fully comply with the Ph. Eur. monograph 2910 (including an update to the open part of EMEA/ASMF/01133). B.I.b.1.c, IA - 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: To add Residue on ignition, Purity and Capacity for caramel decoloration to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Capacity for decomposing neutral salt to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Identification test to the specifications of one of the starting materials. B.I.b.1.c, IA - 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: To add Identification to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Assay to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Assay to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Description test and Nitrates to the specifications of one of the reagents. B.I.b.1.d, IA - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter ‘heavy metals’ from the specifications of the active substance Trifluridine (FTD). B.I.b.1.d, IA - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter ‘heavy metals’ from the specifications of the active substance Tipiracil Hydrochloride (TPI). B.II.d.1.d, IA - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter: To delete the non-significant parameter ‘elemental impurities’ from the specifications of the finished product. Введення змін протягом 6-ти місяців після затвердження. A.7, IA - Administrative change - Deletion of manufacturing sites: To delete the manufacturing site responsible for elemental impurity testing of the finished product Sumika Chemical Analysis Service, Ltd., 3-1-135, Kasugadenaka, Konohana-ku Osaka 554-0022 JAPAN (JPN). A.7, IA- Administrative change - Deletion of manufacturing sites: To delete ‘Anderson Brecon (UK) Limited (Trading as PCI); Unit 1, Talgarth Business park, Trefecca Road Talgarth, Brecon, Powys, LD3 0PQ, United Kingdom’ as a site responsible for Primary and Secondary Packaging of the finished product. A.7, IA- Administrative change - Deletion of manufacturing sites: To delete ‘Anderson Brecon (UK) Limited (Trading as PCI); Units 2-7, Wye Valley Business Park, Brecon Road, Hay-on-Wye, Hereford HR3 5PG, United Kingdom’ as a site responsible for Secondary Packaging, QC testing and QP release of the finished product. | *за рецептом* | UA/16712/01/02 |
|  | **ЛАНСУРФ® 20 МГ/8,19 МГ** | таблетки, вкриті плівковою оболонкою, по 20 мг/8,19 мг, по 10 таблеток у блістері; по 2 або 6 блістерів у коробці з картону | Лє Лаборатуар Серв'є | Францiя | відповідальний за виробництво, контроль якості та випуск серії продукції in bulk:Тайхо Фармасьютікал Ко., Лтд., Японiя;відповідальний за контроль якості, первинне та вторинне пакування і випуск серії готового лікарського засобу:Лабораторії Серв'є Індастрі, Францiя | Японія/Франція | внесення змін до реєстраційних матеріалів: A.7, IA - Administrative change - Deletion of manufacturing sites: To delete sites not involved in routine manufacturing and testing of the active substance trifluridine, namely Laboratories or Facilities for Analytical Method Development (section 3.2.S.2.1.4), Laboratories or Facilities for Analytical Method Validation (section 3.2.S.2.1.5), and Laboratories or Facilities for Stability Study (section 3.2.S.2.1.6). In addition, the MAH and the ASMFH have taken the opportunity to introduce editorial changes as listed in the present / proposed table of the respective summary documents. B.I.d.1.a.4, IB - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data: To extend the re-test period of the active substance trifluridine from 36 months to 48 months with no special storage. B.I.b.2.e, IB- Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate: To replace the GC (method A) test procedure with revised GC method for the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), methanol, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), ethanol, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), acetone, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), isopropyl ether, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method A), chloroform, from the specifications of the active substance trifluridine. B.I.b.1.d, IB- Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter residual solvent (measured by GC method B), pyridine, from the specifications of the active substance trifluridine. B.III.2.a.1, IAin - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State – AS: To change the specification for the active substance trifluridine to fully comply with the Ph. Eur. monograph 2910 (including an update to the open part of EMEA/ASMF/01133). B.I.b.1.c, IA - 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: To add Residue on ignition, Purity and Capacity for caramel decoloration to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Capacity for decomposing neutral salt to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Identification test to the specifications of one of the starting materials. B.I.b.1.c, IA - 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: To add Identification to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Assay to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Assay to the specifications of one of the reagents. B.I.b.1.c, IA - 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: To add Description test and Nitrates to the specifications of one of the reagents. B.I.b.1.d, IA - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter ‘heavy metals’ from the specifications of the active substance Trifluridine (FTD). B.I.b.1.d, IA - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter): To delete the non-significant parameter ‘heavy metals’ from the specifications of the active substance Tipiracil Hydrochloride (TPI). B.II.d.1.d, IA - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter: To delete the non-significant parameter ‘elemental impurities’ from the specifications of the finished product. Введення змін протягом 6-ти місяців після затвердження. A.7, IA - Administrative change - Deletion of manufacturing sites: To delete the manufacturing site responsible for elemental impurity testing of the finished product Sumika Chemical Analysis Service, Ltd., 3-1-135, Kasugadenaka, Konohana-ku Osaka 554-0022 JAPAN (JPN). A.7, IA- Administrative change - Deletion of manufacturing sites: To delete ‘Anderson Brecon (UK) Limited (Trading as PCI); Unit 1, Talgarth Business park, Trefecca Road Talgarth, Brecon, Powys, LD3 0PQ, United Kingdom’ as a site responsible for Primary and Secondary Packaging of the finished product. A.7, IA- Administrative change - Deletion of manufacturing sites: To delete ‘Anderson Brecon (UK) Limited (Trading as PCI); Units 2-7, Wye Valley Business Park, Brecon Road, Hay-on-Wye, Hereford HR3 5PG, United Kingdom’ as a site responsible for Secondary Packaging, QC testing and QP release of the finished product. | *за рецептом* | UA/16712/01/01 |