



JFDA-RDU&PV- AML31122019  
Version 10.0

## List of Medicinal Products Under Additional Monitoring

### Related Information

[Additional monitoring explained:](#)

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\\_topics/document\\_listing/document\\_listing\\_000365.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp)

Brand Name	Active Ingredient	Reason	Registration Date in Jordan	Column1
Amgevita	Adalimumab	New biological	08/04/2019	
Praluent 150mg solution for injection	Alirocumab	New Active Substance	16/06/2018	
Tecentriq	Atezolizumab	New Active Substance	25/03/2018	
Blinicyto	Blinatumomab	New Active Substance	25/04/2017	
Volopem	Bosutinib	Authority Required**	06/10/2019	
Cabometyx	Cabozantinib	New Active Substance	20/03/2018	
Kyprolis	Carfilzomib	New Active Substance	14/05/2017	
Zavicefta	Ceftazidime / avibactam	New active substance	06/02/2019	
Zevtera 500 mg powder for concentrate for solution for infusion	Ceftobiprole medocaril sodium	New active substance	11/10/2018	
Zerbaxa	Ceftolozane / tazobactam	New active substance	29/11/2017	
Combined hormonal contraceptives containing chlormadinone	Chlormadinone Ethinylestradiol, Chlormadinone Acetate Ethinylestradiol	PASS		

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Cyproterone acetate and Ethinylestradiol containing medicinal products (For full list of products see Annex I)	Cyproterone acetate and Ethinylestradiol	PASS		
<del>Daklinza</del>	<del>Daclatasvir</del>	<del>New Active Substance, PASS</del>	<del>15/11/2016</del>	
Darzalex 100mg/5ml	Daratumumab	New Active Substance	05/11/2017	
Exviera	Dasabuvir	New Active Substance, PASS	30/08/2015	
Elpida 20, 50, 70, 140 mg tablet	Dasatinib	Authority Required**	02/04/2018	
Exjade	Deferasirox	PASS	20/06/2006	
Hemlibra	Emicizumab	New active substance and <i>new biological</i>	11/02/2019	
Glyxambi	Empagliflozin/linagliptin	New active substance	15/08/2018	
Synjardy	Empagliflozin/metformin	New Active Substance	10/12/2017	
Joxane PFS	Enoxaparin	Biosimilar	13/10/2019	
Steglatro	Ertugliflozin	New active substance	16/05/2019	
Repatha	Evolocumab	New active substance and <i>new biological</i>	30/08/2016	
Intravenous iron-containing medicinal products	Ferric carboxymaltose, iron dextran, sodium ferric gluconate, iron	PASS		
Gilenya	Fingolimod	PASS	15/04/2012	
Melior	Fingolimod	Postmarketing Surveillance	25/04/2017	Postmarketing Surveillance
Tremfya 100mg/ml PFS	Guselkumab	New Active Substance	03/10/2019	
Hydroxyethyl starch (HES)-containig products	Hydroxyethyl starch	PASS	.....	
Praxbind	Idarucizumab	New Active Substance	24/01/2018	

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<b>Glivec</b>	Imatinib	PASS	<b>09/12/2004</b>	
<b>Cresemba 200mg vial</b>	Isavuconazole	New Active Substance	<b>31/07/2018</b>	
<b>Harvoni</b>	Ledipasvir/ sofosbuvir	New Active Substance, PASS	<b>21/08/2016</b>	
<b>Revlimid</b>	Lenalidomide	PASS	<b>31/01/2013</b>	
<b>Glyxambi film-coated tablet</b>	Linagliptin+ Empagliflozin	New Active Substance	<b>15/08/2018</b>	
<b>Sotira Capsule</b>	Linalidomide	Authority Required**	<b>10/08/2017</b>	
<b>Lenvima (4, 10) mg Cap</b>	<b>Lenvatinib</b>	<b>New Active Substance</b>	<b>10/11/2019</b>	
<b>Saxenda 6mg/ml solution for inj</b>	Liraglutide	New biological	<b>17/09/2017</b>	
<b>Penthrox</b>	Methoxyflurane	PASS	<b>24/02/2019</b>	
<b>Medikinet retard</b>	Methylphenidate hydrochloride	PASS	<b>16/01/2014</b>	
<b>Rydapt</b>	Midostaurin	New active substance	<b>28/01/2019</b>	
<b>Tysabri</b>	Natalizumab	PASS*	<b>10/11/2008</b>	
<b>Ofev</b>	Nintedanib	New active substance	<b>29/10/2018</b>	
<b>Opdivo</b>	Nivolumab	New Active Substance	<b>14/11/2016</b>	
<b>Ocrevus 300mg/10ml vial</b>	Ocrelizumab	New Active Substance	<b>25/07/2018</b>	
<b>Viekirax</b>	Ombitasvir/Paritaprevir/ ritonavir	New Active Substance, PASS*	<b>03/09/2015</b>	
<b>Tagrisso FCT</b>	Osimertinib	New Active Substance	<b>08/03/2018</b>	
<b>Ibrance 100mg</b>	Palbociclib	New Active Substance	<b>17/07/2017</b>	
<b>Keytruda</b>	Pembrolizumab	New Active Substance	<b>03/08/2016</b>	
<b>Iclusig</b>	Ponatinib	PASS <sup>1</sup>	<b>14/04/2019</b>	
<b>Kisqali FCT</b>	Ribociclib	New Active Substance	<b>11/01/2018</b>	
<b>Truxima</b>	Rituximab	New biological	<b>20/01/2019</b>	

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<b>Tromax 10mg/ml</b>	Rituximab	Authority Required**	<b>18/03/2018</b>	Postmarketing Surveillance
<b>Xarelto</b>	Rivaroxaban	PASS*	<b>07/12/2009</b>	
<b>Xavir</b>	Rivaroxaban	PASS*	<b>13/05/2019</b>	
<b>Entresto</b>	Sacubitril/valsartan	New Active Substance	<b>10/02/2016</b>	
<b>Valproate and related substances (sodium valproate, valproic acid, valproate semisodium, valpromide- containing medicinal products)</b>	Sodium valproate, valproic acid, valproate semisodium, valpromide	PASS		
<b>Grateziano</b>	Sofosbuvir	PASS	<b>26/12/2018</b>	
<b>Epclusa</b>	Sofosbuvir/velpatasvir	New active substance	<b>03/01/2019</b>	
<b>Targocid and associated names</b>	Teicoplanin	PASS*		
<b>Vemlidy</b>	Tenofovir alafenamide	New active substance	<b>11/04/2019</b>	
<b>Thiocolchicoside-containing medicinal products</b>	Thiocolchicoside	PASS		
<b>Spiolto Respimat</b>	Tiotropium Bromide Monohydrate / Olodaterol Hydrochloride	New active substance	<b>30/08/2018</b>	
<b>Xeljanz</b>	Tofacitinib	New Active Substance	<b>15/05/2016</b>	
<b>Herzuma</b>	Trastuzumab	New biological	<b>05/05/2019</b>	
<b>Lonsurf</b>	Trifluridine / tipiracil	New active substance	<b>17/04/2018</b>	
<b>Anoro Ellipta 62.5mcg/25mcg</b>	Vilanterol/Umeclidinium	New Active sub/PASS*	<b>06/09/2017</b>	

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\*the company that markets the medicine is required to carry out additional studies, for instance, to provide more data on long-term use of the medicine or on a rare side effect seen during clinical trials.

\*\* JFDA requires to be additionally monitored

 **Added**       **Removed**