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Safety Updates						
No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
1	Aldactone	Spironolactone	Interaction with other medicinal products and other forms of interaction	Addition of text to read "Spironolactone may reduce mitotane plasma levels in adrenocortical carcinoma patients and should not be used concomitantly. Like other diuretics, spironolactone reduces the renal clearance of lithium, thus increasing the risk of lithium toxicity. Monitor lithium levels periodically when spironolactone is co-administered."	09/06/2025	Pfizer
2	Glyxambi	Empagliflozin + Linagliptin	Interaction with other medicinal products and other forms of interaction	Addition of text under sub-section Effects of empagliflozin on other medicinal products to read "Empagliflozin may increase renal lithium excretion and the blood lithium levels may be decreased. Serum concentration of lithium should be monitored more frequently after empagliflozin initiation and dose changes. Please refer the patient to the lithium prescribing doctor in order to monitor serum concentration of lithium.	18/07/2025	Boehringer-ingelheim /Ernest Chemists

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2	Glyxambi	Empagliflozin + Linagliptin	Undesirable effects / Possible side effects	Addition of text “Tubulointerstitial nephritis” under the system organ class “Renal and urinary disorders,” with a frequency of “Very rare,” to be included in the subsection “Adverse Reactions.” Addition of text to read "inflammation of the kidneys (tubulointerstitial nephritis)" under sub-section seen very rarely Addition of text “Constipation” under the system organ class “Gastrointestinal disorders” with a frequency of “Common,” to be included in the sub-section “Adverse Reactions.”	18/07/2025	Boehringer-ingelheim /Ernest Chemists

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3	Hemlibra	Emicizumab	Special Warnings and Precautions For Use	Addition of sub-title to include “educational materials”. Addition of text to read under the sub-section educational materials, “All physicians who are expected to prescribe, use or oversee the administration of Hemlibra must ensure they have received and are familiar with the physician educational material. Healthcare professionals must explain and discuss the benefits and risks of Hemlibra therapy with the patient and their caregivers and ensure the patient card, and patient/carer guide, are provided. The patient/caregiver should be instructed to carry the patient card at all times and show it to any other healthcare professional consulted.”	04/08/2025	Roche
			Undesirable Effects	Addition of text under the sub-section Tabulated List of Adverse Drug Reactions to include the System Organ Class (SOC) Immune System Disorders under Adverse Reactions (preferred term, MedDRA), with the inclusion of Hypersensitivity at the frequency ‘Uncommon’.”		

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4	Micardis	40 mg telmisartan.	Special warnings and precautions for use	Addition of text to read "Intestinal angioedema has been reported in patients treated with angiotensin II receptor antagonists (see section 4.8). These patients presented with abdominal pain, nausea, vomiting and diarrhoea. Symptoms resolved after discontinuation of angiotensin II receptor antagonists. If intestinal angioedema is diagnosed, telmisartan should be discontinued and appropriate monitoring should be initiated until complete resolution of symptoms has occurred.	17/07/2025	Boehringer-ingelheim /Ernest Chemists
			Undesirable effects	Addition of text to read "Cases of intestinal angioedema have been reported after the use of angiotensin II receptor antagonists (see section 4.4).		

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5	Jardiance	Empagliflozin	Special population	Revision of text to read "The recommended starting dose is 10 mg empagliflozin once daily. In patients tolerating empagliflozin 10 mg once daily and requiring additional glycaemic control, the dose can be increased to 25 mg once daily (see sections 5.1 and 5.2). No data are available for children with eGFR <60 ml/min/1.73 m² and children below 10 years of age. The safety and efficacy of empagliflozin for the treatment of heart failure or for the treatment of chronic kidney disease in children under 18 years of age have not been established. No data are available." Revision of text under Children and adolescents to read "Jardiance can be used in children aged 10 years and older for the treatment of type 2 diabetes. No data are available in children below 10 years of age. Jardiance is not recommended for children and adolescents under 18 years of age for the treatment of heart failure or for the treatment of chronic kidney disease, because it has not been studied in these patients."	18/07/2025	Boehringer-ingelheim /Ernest Chemists

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6	Jardiance	Empagliflozin	4.4 Special warnings and precautions for use	Addition of sub-title to include "General" Addition of text to read "Empagliflozin should not be used in patients with type 1 diabetes mellitus (see “ketoacidosis” in section 4.4)" Under sub title General	18/07/2025	Boehringer-ingelheim /Ernest Chemists
			Undesriable effects	Addiition of text to read "In the DINAMO trial 157 children aged 10 years and above with type 2 diabetes were treated, in which 52 patients received empagliflozin, 52 linagliptin and 53 placebo (see section 5.1). During the placebo-controlled phase, the most frequent adverse drug reaction was hypoglycaemia with higher overall rates for patients in the empagliflozin pooled group compared with placebo (empagliflozin 10 mg and 25 mg, pooled: 23.1%, placebo: 9.4%). None of these events was severe or required assistance. Overall, the safety profile in children was similar to the safety profile in adults with type 2 diabetes mellitus.		

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6	Jardiance	Empagliflozin	Section 2- What you need to know before you take Jardiance	Addition of text to read "If you suspect you have ketoacidosis, contact a doctor or the nearest hospital straight away and stop taking this medicine until further advice from your doctor."	18/07/2025	Boehringer-ingelheim /Ernest Chemists
7	Pagenax	Brolucizumab	Dosage regimen and administration	Addition of sub title "Proliferative Diabetic Retinopathy (PDR)" Addition of text to read "The recommended dose for Beovu is 6 mg (0.05 mL) administered by intravitreal injection every 6 weeks for the first three doses. Thereafter, Beovu is administered every 12 weeks (3 months). The physician may individualize treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. The treatment interval between two doses should not be less than 8 weeks (2 months) (see sections 6 Warnings and precautions and 12 Clinical studies) [35]." Under sub title Proliferative Diabetic Retinopathy (PDR)	17/07/2025	Novartis

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7	Pagenax	Brolucizumab	Adverse drug reactions	Addition of text under sub title Proliferative Diabetic Retinopathy (PDR) Population to read "The safety of Beovu up to 1 year was evaluated in the pooled data of 599 patients treated with the recommended dose of brolucizumab 6 mg, including 347 PDR patients from Phase III CONDOR study and 252 patients with diabetic retinopathy (DR) (moderate to severe non-PDR or PDR) from KESTREL and KITE studies [35].	17/07/2025	Novartis
			Adverse drug reactions	The ocular and non-ocular events in the pooled DR population were reported with frequency and severity similar to those seen in the wet AMD and DME studies. Similar to DME, the adverse drug reactions of iridocyclitis and vitreous hemorrhage were also observed at a higher frequency (category of common) in the pooled DR population as compared to the pooled nAMD. In addition, the adverse drug reactions of retinal vascular occlusion and retinal vasculitis were each reported in one patient (0.2%, category of uncommon) treated with Beovu in the pooled DR population [35]. "		

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8	Tecentriq	Atezolizumab	Undesirable Effects	Addition of text under Skin and Subcutaneous Tissue Disorders in the section Therapy of Adverse Reactions, with the frequency categories Uncommon and Rare, to include the preferred term Lichen Disorders.”	06/08/2025	Roche
9	Trajenta	Linagliptin	Section 3- Children and adolescents	Revision of text to read "Trajenta is not recommended for children and adolescents under 18 years. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years."	18/07/2025	Boehringer-ingelheim /Ernest Chemists
			4.8- Undesirable effects	Addition of text under sub-section paediatric population to read "Overall, in clinical trials in paediatric patients with type 2 diabetes mellitus aged 10 to 17 years, the safety profile of linagliptin was similar to that observed in the adult population.		

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9	Trajenta	Linagliptin	Section 5.2-Pharmacokinetic properties	Addition of text under sub-section paediattric population "A paediatric Phase 3 study examined pharmacokinetics and pharmacodynamics (HbA1c change from baseline) of 5 mg linagliptin in children and adolescents 10 to 17 years of age with type 2 diabetes mellitus. The observed exposure-response relationship was generally comparable between paediatric and adult patients, however, with a smaller drug effect estimated in children. Oral administration of linagliptin resulted in exposure within the range observed in adult patients. The observed geometric mean trough concentrations and geometric mean concentrations at 1.5 hours post-administration (representing a concentration around tmax) at steady state were 4.30 nmol/L and 12.6 nmol/L, respectively. Corresponding plasma concentrations in adult patients were 6.04 nmol/L and 15.1 nmol/L.	18/07/2025	Boehringer-ingelheim /Ernest Chemists

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10	Twynsta	Telmisartan/ Amlodipine	Section 2- What you need to know before you take Twynsta	Addition of text to read "Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Twynsta. Your doctor will decide on further treatment. Do not stop taking Twynsta on your own."	17/07/2025	Boehringer-ingelheim /Ernest Chemists
			Section 4 -Possible side effects	Addition of text to nread "Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products."		
			Section 4 -Possible side effects	Addition of text to read "Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products."		

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10	Twynsta	Telmisartan/ Amlodipine	Section 4.4 Special warnings and precautions for use	Addition of text to read "Intestinal angioedema Intestinal angioedema has been reported in patients treated with angiotensin II receptor antagonists (see section 4.8). These patients presented with abdominal pain, nausea, vomiting and diarrhoea. Symptoms resolved after discontinuation of angiotensin II receptor antagonists. If intestinal angioedema is diagnosed, telmisartan should be discontinued and appropriate monitoring should be initiated until complete resolution of symptoms has occurred.	17/07/2025	Boehringer-ingelheim /Ernest Chemists