

The underlisted safety variations have been submitted by Marketing Authorization Holders (MAHs) and approved by the Food and Drugs Authority in line with the Variation Guidelines for Allopathic Medicines. These safety variations are being shared with healthcare professionals and patients.

Safety Updates						
No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
1	Aspirin Cardio	Acetylsalicylic acid	Pregnancy, lactation	Addition of text under sub-section First and second trimester to include "If acetylsalicylic acid is used by a woman who is trying for a baby, or if it is used during the first or second trimester of pregnancy, the dose should be kept as low and the duration of treatment as short as possible."	4/2/2026	Roche
			Undesirable effects	Addition of text under subsection uncommon to read "Formation of intestinal diaphragm-like structures, particularly with long-term use (intestinal diaphragm disease)."		
			Contraindications	Addition of text to read " <ul style="list-style-type: none"> <li>• Active gastric and/or duodenal ulcers or gastrointestinal haemorrhage. Inflammatory gastrointestinal diseases (such as Crohn's disease, ulcerative colitis).</li> <li>• Severe liver dysfunction (liver cirrhosis and ascites).</li> <li>• Severe renal dysfunction (creatinine clearance &lt;30 mL/min).</li> <li>• Severe heart failure (NYHA III-IV)."</li> </ul>		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
2	CellCept	Mycophenolate Mofetil	Contraindications	Revision of text to read "Known hypersensitivity, including anaphylaxis, to mycophenolate mofetil, mycophenolic acid or any of the excipients listed under "Composition" (see "Warnings and precautions")."	11/2/2026	Roche
			Warnings and precautions	<p>Addition of sub-title to include "Hypersensitivity reactions."</p> <p>Addition of text under sub-title Hypersensitivity reactions to read "In post-marketing experience, cases of severe hypersensitivity reactions, including angioedema and anaphylaxis, have been reported during mycophenolate mofetil treatment with or without adjunctive therapy, premedication, and/or a history of hypersensitivity reactions. These reactions usually occurred within minutes to up to one day after starting mycophenolate mofetil treatment. It is recommended that mycophenolate mofetil be permanently discontinued if signs or symptoms of an anaphylactic reaction occur. The patient should receive appropriate medical treatment immediately and be monitored until symptoms resolve (see "Contraindications" and "Undesirable effects")."</p>		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
2	CellCept	Mycophenolate Mofetil	Post-marketing experience	Addition of text under sub-section immune system disorders to read "Not known: Severe hypersensitivity reactions, including angioedema and anaphylactic reaction."	11/2/2026	Roche
3	Co- Micardis	Telmisartan/ Hydrochlorothiazide	Special warnings and precautions for use	Addition of text under sub-section intestinal angioedema 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."	15/01/2026	Boehringer - Ingelheim
			Undesirable effects	Addition of text under sub-section intestinal angioedema to read "Cases of intestinal angioedema have been reported after the use of angiotensin II receptor antagonists (see section 4.4)."		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
4	Ocrevus	Ocrelizumab	Warnings and precautions	<p>Addition of text under sub-section liver injury to read "Clinically significant liver injury, without detection of viral hepatitis, has been observed rarely in the post-marketing setting in patients treated with Ocrevus. Signs of liver injury, including markedly elevated serum hepatic enzymes with elevated total bilirubin, have occurred from days to months after administration of the first dose. Patients treated with Ocrevus found to have an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 3x the upper limit of normal (ULN) with serum total bilirubin greater than 2x ULN are potentially at risk for severe drug-induced liver injury and should be evaluated for liver injury. If liver injury is present, ocrelizumab must be discontinued. If an alternative etiology is identified, treatment with ocrelizumab can be resumed only when the liver injury has fully resolved.</p>	13/03/2026	Roche

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
4	Ocrevus	Ocrelizumab	Warnings and precautions	Liver function tests (ALT, AST, alkaline phosphatase and total bilirubin) should be performed before initiation of treatment with Ocrevus, and patients should be monitored for signs and symptoms of any hepatic injury during treatment. Serum aminotransferases, alkaline phosphatase, and bilirubin levels should be measured in patients who report symptoms that may indicate liver injury, including new or worsening fatigue, anorexia, nausea, vomiting, right upper abdominal discomfort, dark urine, or jaundice.	13/03/2026	Roche
			Undesirable effects	Addition of the adverse reaction "liver injury" under the sub-section "Hepatobiliary Disorders," with a frequency of "rare."		
5	Rocephin	Ceftriaxone	Warnings and precautions	Addition of text to read "Jarisch-Herxheimer reaction (JHR). In some patients with spirochaetal infections, a Jarisch-Herxheimer reaction (JHR) may occur shortly after starting treatment with ceftriaxone. The JHR is normally self-limiting or can be managed symptomatically. If such a reaction occurs, antibiotic treatment should not be discontinued."	11/2/2026	Roche

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
5	Rocephin	Ceftriaxone	Undesirable effects	Addition of text under sub-section General disorders and administration site conditions to read "Not known: Jarisch-Herxheimer reaction."	11/2/2026	Roche
6	Synjardy	Empagliflozin and Metformin Hydrochloride	Special warnings and precautions for use	<p>Addition of text to read "Prolonged diabetic ketoacidosis and prolonged glucosuria have been observed with empagliflozin. Diabetic ketoacidosis may last longer after discontinuation of empagliflozin than expected from the plasma half-life (see section 5.2). Empagliflozin-independent factors, such as insulin deficiency, might be involved in prolonged periods of diabetic ketoacidosis.</p> <p>Revision of text to include under sub-section Elevated haematocrit to read "Haematocrit increase was observed with empagliflozin treatment (see section 4.8). Patients with pronounced elevations in haematocrit should be monitored and investigated for underlying haematological disease.</p>	9/1/2026	Boehringer - Ingelheim

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
6	Synjardy	Empagliflozin and Metformin Hydrochloride	Special warnings and precautions for use	<p>Addition of text to include under sub-section Vaginal moniliasis, vulvovaginitis, balanitis and other genital infection to read "Cases of phimosis/acquired phimosis have been reported concurrent with genital infections and in some cases, circumcision was required.</p> <p>Addition of text to read "Patients with known or suspected mitochondrial diseases In patients with known mitochondrial diseases such as Mitochondrial Encephalopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD), metformin is not recommended due to the risk of lactic acidosis exacerbation and neurologic complications which may lead to worsening of the disease. In case of signs and symptoms suggestive of MELAS syndrome or MIDD after the intake of metformin, treatment with metformin should be withdrawn immediately and prompt diagnostic evaluation should be performed.</p>	9/1/2026	Boehringer - Ingelheim

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
7	Tagrisso	Osimertinib	<p>What TAGRISSO is and what it is used for</p>	<p>Addition of text to read "TAGRISSO can be prescribed for you, in combination with other anti-cancer medicines, including:</p> <ul style="list-style-type: none"> <li>• pemetrexed and a platinum- containing chemotherapy, as the first medicine you receive for your cancer which has spread to other parts of the body.</li> </ul> <p>When TAGRISSO is given in combination with other anti-cancer medicines, it is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines,ask your doctor."</p>	1/16/2026	AstraZeneca
			<p>How to take TAGRISSO</p>	<p>Addition of text under sub-section How much to take to read "</p> <ul style="list-style-type: none"> <li>• The recommended dose is one 80 mg tablet each day when TAGRISSO is taken alone</li> <li>• The recommended dose of TAGRISSO is one 80 mg tablet each day when taken with pemetrexed and a platinum-containing chemotherapy." </li></ul>		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
7	Tagrisso	Osimertinib	Possible side effects	<p>Addition of text to be included under the sub-section: The following side effects have been reported in a clinical trial in patients receiving TAGRISSO in combination with pemetrexed and a platinum-containing chemotherapy: Very common (may affect more than 1 in 10 people)Diarrhoea - this may come and go during treatment. Tell your doctor if your diarrhoea does not go away or becomes severe.</p> <ul style="list-style-type: none"> <li>• Skin and nail problems - signs may include pain, itching, dry skin, rash, redness around the fingernails. This is more likely in areas exposed to the sun. Using moisturisers regularly on your skin and nails can help with this. Tell your doctor if your skin or nail problems get worse.</li> <li>• Stomatitis - inflammation of the inner lining of the mouth or ulcers forming in the mouth.</li> <li>• Loss of appetite.</li> <li>• Reduction in the number of white blood cells (leukocytes, lymphocytes or neutrophils).</li> <li>• Increase of a substance in the blood called creatinine (produced by your body and removed by the kidney).</li> </ul>	1/16/2026	AstraZeneca

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
7	Tecentriq	Atezolizumab	Undesirable effects	<p>Addition of text under the System Organ Class “Infections and Infestations,” with the frequency category “Rare,” to include “Cytomegalovirus infection” for both Atezolizumab monotherapy and Atezolizumab combination therapy sub-sections.</p> <p>Addition of “Sarcoidosis” (frequency: Rare) under the System Organ Class “Immune System Disorders” for the Atezolizumab monotherapy sub-section.</p> <p>Addition of text under the System Organ Class “Eye Disorders,” with the frequency classified as “Uncommon,” to include “Uveitis” under the sub-section on Atezolizumab monotherapy.</p> <p>Addition of text under the System Organ Class “Eye Disorders,” with the frequency classified as “Rare,” to include “Uveitis” under the sub-section on Atezolizumab combination therapy</p>	3/2/2026	Roche

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
7	Tecentriq	Atezolizumab	Undesirable effects	<p>Addition of text under the System Organ Class "Musculoskeletal and Connective Tissue Disorders," with the frequency classified as "Common," to include "Arthritis" for the sub-sections on Atezolizumab monotherapy and Atezolizumab combination therapy</p> <p>Addition of text under the System Organ Class "Musculoskeletal and Connective Tissue Disorders," with the frequency classified as "Uncommon," to include "Tenosynovitis" for the sub-sections on Atezolizumab monotherapy and Atezolizumab combination therapy</p>	3/2/2026	Roche