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.

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
1	Azarga	Brinzolamide / timolol	Warnings and precautions	Revision of text under the heading General to read "Hypersensitivity reactions reported with sulphonamide derivates, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur in patients receiving Azarga as it is absorbed systemically. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs of serious reactions or hypersensitivity occur, use of this product should be discontinued immediately. "	17/06/2022	Norvatis
			Adverse drug reactions	Addition of the adverse drug reaction "Stevens-Johnson syndrome (SJS), Toxic epidermal necrolysis (TEN)," under the System organ classification Skin and subcutaneous tissue disorders under the heading Adverse drug reactions from spontaneous reports and literature (frequency not known)		
2	Azopt	Brinzolamide 10mg/ml eye drops suspension	Warnings and Precautions	Revision of text under subtitle General to read "Like other topically applied ophthalmic agents, brinzolamide is absorbed systemically. Systemic absorption can be minimized by nasolacrimal occlusion (see section DOSAGE REGIMEN AND ADMINISTRATION). Hypersensitivity reactions reported with sulphonamide derivatives, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur in patients receiving Azopt as it is absorbed systemically. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs of serious reactions or hypersensitivity occur, use of this product should be discontinued immediately. Acid-base disturbances have been reported with oral carbonic anhydrase inhibitors. Azopt should be used with caution in patients with risk of renal impairment because of the possible risk of metabolic acidosis. The possible role of brinzolamide on corneal endothelial function has not been investigated in patients with compromised corneas (particularly in patients with low endothelial cell count). Carbonic anhydrase inhibitors may affect corneal hydration, which may lead to a corneal decompensation and edema. Careful monitoring of patients with compromised corneas, such as patients with diabetes mellitus or corneal dystrophies, is recommended."	17/06/2022	Novartis
			Adverse Drug Reactions	Insertion of text under subtitle Table 2 Adverse drug reactions from spontaneous reports and literature(frequency not known) to read" System organ classification;Skin and subcutaneous tissue diorders with adverse drug reaction;Stevens-Johnson syndrome(SJS), Toxic epiderman necrolysis(TEN)"		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
2	Azopt	Brinzolamide 10mg/ml eye drops suspension	Storage	Revision of text to read "See folding box. Azopt should not be used after the date marked “EXP” on the pack. Azopt must be kept out of the sight and reach of children."	17/06/2022	Novartis
3	Edurant	Rilpivirine	Posology and method of administration	Addition of the heading "Missed dose(s)" under this section. Addition of the text "If the patient misses a dose of EDURANT within 12 hours of the time it is usually taken, the patient should take EDURANT with a meal as soon as possible and then take the next dose of EDURANT at the regularly scheduled time. If a patient misses a dose of EDURANT by more than 12 hours, the patient should not take the missed dose, but resume the usual dosing schedule." under the heading Missed dose(s) Addition of the heading "Special populations" under this section Addition of the text "Pediatrics (12 to 17 years) The recommended dose of EDURANT is one 25 mg tablet once daily taken orally with a meal (see Pharmacokinetic properties)." under the heading Special populations Deletion of the heading "Missed dose(s)" under this section. Deletion of the text "If the patient misses a dose of EDURANT within 12 hours of the time it is usually taken, the patient should take EDURANT with a meal as soon as possible and then take the next dose of EDURANT at the regularly scheduled time. If a patient misses a dose of EDURANT by more than 12 hours, the patient should not take the missed dose, but resume the usual dosing schedule." under the heading Missed dose(s)	27/6/2022	Johnson and Johnson
			Special warnings and precautions for use	Deletion of the heading "Fat redistribution" under this section. Deletion of the text "Redistribution/accumulation of body fat, including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and “cushingoid appearance” have been observed in patients receiving antiretroviral therapy. The mechanism and long term consequences of these events are currently unknown. A causal relationship has not been established (see section 4.8)." under the heading Fat redistribution.		
			Fertility, pregnancy and lactation	Deletion of the subheading "Women of childbearing potential" under the heading Pregnancy. Deletion of the text "Since there are no adequate and well controlled clinical studies with EDURANT in pregnant women, adequate contraception is recommended for women of childbearing potential when taking EDURANT" under the subheading Women of childbearing potential.		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
3	Edurant	Rilpivirine	Undesirable effects	Deletion of heading "Lipodystrophy" under this section Deletion of the text "Combination antiretroviral therapy (CART) has been associated with redistribution of body fat (lipodystrophy) in HIV infected patients, including loss of peripheral and facial subcutaneous fat, increased intra abdominal and visceral fat, breast hypertrophy and dorsocervical fat accumulation (buffalo hump)." under the heading Lipodystrophy	27/06/2022	Johnson and Johnson
4	Elocom	Mometasone furoate	Special warnings and precautions for use	Addition of the text "Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered." under this section	7/4/2022	Merck
			Undesirable effects	Addition of the adverse reaction "Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules (see section 4.4)." under the frequency Not known under the system class Skin and subcutaneous tissue disorders		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
5	Herceptin	Trastuzumab	Posology and method of administration	Revision of text to read "In order to prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is Herceptin (trastuzumab) and not (another trastuzumab-containing product (e.g. trastuzumab emtansine or trastuzumab deruxtecan)" under the heading "posology and method of administration". Revision of text to read "During the treatment course with Herceptin subcutaneous formulation other medicinal products for subcutaneous administration should preferably be injected at different sites. Patients should be observed for 30 minutes after the first injection and for 15 minutes after subsequent injections for signs or symptoms of administration-related reactions " under the subheading "method of administration". Revision of text to read "Herceptin subcutaneous formulation, caution should be exercised as these have been associated with the intravenous formulation. Patients should be observed for ARRs for 30 minutes after the first injection and for 15 minutes after subsequent injections. ARRs considered mild in severity can be treated with an analgesic/antipyretic such as meperidine or paracetamol, or an antihistamine such as diphenhydramine. Serious reactions to intravenous Herceptin have been treated successfully with supportive therapy such as oxygen, beta-agonists, and corticosteroids. In rare cases, these reactions were associated with a clinical course culminating in a fatal outcome. Patients experiencing dyspnoea at rest due to complications of advanced malignancy and comorbidities may be at increased risk of a fatal ARR. Therefore, these patients should not be treated with Herceptin" under the subheading "administration related reactions". Addition of subheading "sodium" Addition of text "Herceptin contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium-free" under the subheading "sodium".	26/05/2022	Roche Ltd
			Shelf life	Addition of text "21 months" under the heading "shelf life". Revision of text to read "Once transferred from the vial to the syringe the medicinal product is physically and chemically stable for 28 days at 2°C – 8°C and for 6 hours (cumulative time in the vial and the syringe) at ambient temperature (max. 30°C) in diffused daylight. As Herceptin does not contain any antimicrobial-preservative, from a microbiological point of view, the medicine should be used immediately.		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
5	Herceptin	Trastuzumab	Special precautions for disposal and other handling	Deletion of text "6.7 Packs, Vial 600 mg/5 mL, this is a medicament. A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription without consulting your doctor. Medicine: keep out of reach of children" under the heading "special precautions for disposal and other handling"	26/05/2022	Ro0che Ltd
6	Hydroxyurea	hydroxycarbamide 500mg hard capsule and film-coated tablet	Special warnings and precautions for use	Revision of text to read "Cases of hemolytic anemia in patients treated with hydroxycarbamide for myeloproliferative diseases have been reported. Patients who develop severe anemia should have laboratory tests evaluated for hemolysis. If diagnosis of hemolytic anemia is established, hydroxycarbamide should be discontinued."	6/7/2022	Novartis
			Undesirable effects	Revision of text to read under the heading Blood and lymphatic system disorders "Not known: Hemolytic anemia"		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
7	Hydroxyurea	Hydroxycarbamide 100mg&1000mg hard capsule and film-coated tablet	Special warnings and precautions for use	Revision of text to read"Hydroxycarbamide may cause bone marrow depression with leukopenia being the first and most common sign of bone marrow inhibition. Thrombocytopenia and anaemia occur less frequently and rarely without preceding leukopenia. A differential blood count, which determines haemoglobin content, leucocyte differentiation and platelet count, should be performed regularly, even after adjustment to the individually optimal dose. The control interval should be individually adjusted, but normally the control should be performed once a week. If the leukocyte count falls below 2.5 × 109/l or the platelet count falls below 100 ×109/l, therapy should be interrupted until the values have largely returned to normal (see section 4.2). The bone marrow depression regresses when therapy is discontinued." Addition of text to read"Cases of haemolytic anemia in patients treated with hydroxycarbamide for myeloproliferative diseases have been reported. Patients who develop severe anemia should have laboratory tests evaluated for haemolysis. If diagnosis of hemolytic anemia is established, hydroxycarbamide should be discontinued." Revision of text under subtitle Respiratory diseases to read"Interstitial lung disease including pulmonary fibrosis, lung infiltration, pneumonitis, and alveolitis/allergic alveolitis have been reported in patients treated for myeloproliferative neoplasm and may be associated with fatal outcome. Patient developing pyrexia, cough, dyspnoea or other respiratory symptoms should be closely monitored, investigated and treated. Promptly discontinue of hydroxycarbamide and treatment with corticosteroids appears to be associated with resolution of the pulmonary events (see section 4.8)"	6/6/2022	Novartis
7	Hydroxyurea	Hydroxycarbamide 100mg&1000mg hard capsule and film-coated tablet	Fertility, pregnancy and lactation	Revision of text under subtitle Pregnancy to read"Hydroxycarbamide is genotoxic. Hydroxycarbamide has been demonstrated to be a potent teratogen in a wide variety of animal models. Embryo-foetal death, foetal malformation of the viscera and the skeleton, growth disorders and functional defects have been observed (see also section 5.3). Hydroxycarbamide can have a hereditary genetic damaging effect. therefore, genetic counseling in advance is also recommended for those wishing to become pregnant after treatment with hydroxycarbamide. Hydroxycarbamide must not be used during pregnancy. In case of a vital indication for the treatment of a pregnant patient specialised consultation should be offered due the potential harm to the foetus. Women must not become pregnant during treatment. Adequate contraceptive measures are to be taken if a partner is treated with hydroxycarbamide (see section 4.4). If pregnancy still occurs during treatment, the possibility of a genetic consultation should be offered due to the potential harm to the foetus."	6/6/2022	Novartis
			Undesirable effects	Revision of text under subtitle Blood and lymphatic system disorders to read"Very common: Bone marrow depression, leucopenia, thrombocytopenia, megaloblastosis, anaemia, CD4 lymphocytes decreased. Not known: Haemolytic anaemia"		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
8	Oxynorm	Oxycodone hydrochloride	What OxyNorm capsules are and what they are used for	Revision of text to read "This medicine has been prescribed for you for the relief of moderate to severe pain. It contains oxycodone which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed for you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely."	20/05/2022	Kama
			What you need to know before you take OxyNorm capsules	Addition of text to read "have increased carbon dioxide levels in the blood. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache"		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
8	Oxynorm	Oxycodone hydrochloride	Warnings and precautions	Addition of text to read "are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs; • have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs; • feel you need to take more capsules to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever • know you are suffering from a brain injury or tumour • feel very lightheaded or faint • have long term pain unrelated to cancer; • have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea" Revision of text to read "have severely impaired lung function. Symptoms may include breathlessness and coughing" Revision and addition of text to read "Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely. . Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death. Do not inject OxyNorm capsules. This can cause serious side effects including tissue death at the site of injection, infection, inflammation of the lungs and damage to the heart which may be fatal"	20/05/2022	Kama

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
8	Oxynorm	Oxycodone hydrochloride	Other medicines and OxyNorm capsules	Revision and addition of text to read of text to read "Taking OxyNorm capsules at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include: • other medicines used to treat pain known as opioids (such as codeine or morphine); • medicines used to treat epilepsy (gabapentinoids) such as pregabalin; • medicines used to treat anxiety. a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not take OxyNorm capsules if you are currently taking this type of medicine, or have taken this medicine in the last two weeks. Because of this, your doctor will only prescribe OxyNorm capsules where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately. Taking OxyNorm capsules with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The symptoms of this include agitation, seeing or hearing things that aren't real (hallucinations), loss of consciousness, a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, stiffness, feeling or being sick, or diarrhoea. If you are taking SSRI or SNRI medicines such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine your doctor may reduce your dose of OxyNorm capsules. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to adjust your dose: •a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline" Delation of text to read " antihistamines; • medicines to treat Parkinson's disease. Also tell your doctor if you have recently been given an anaesthetic." Addition of text to read " • quinidine, a medicine used to treat an irregular heartbeat"	20/05/2022	Kama

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
8	Oxynorm	Oxycodone hydrochloride	Pregnancy and breastfeeding	Addition of text to read under the heading Pregnancy "Do not take OxyNorm capsules if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take OxyNorm capsules during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated"	20/05/2022	kama
			Pregnancy and breastfeeding	Addition of text to read under heading Breast-feeding "Do not take OxyNorm capsules while you are breastfeeding as oxycodone passes into breast milk and will affect your baby."		
			Driving and using machines	Addition of text to read "• Do not drive while taking this medicine until you know how it affects you. • It is an offence to drive if this medicine affects your ability to drive. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.		
			If you stop taking OxyNorm capsules	Addition of text to read "srestlessness, difficulty sleeping, irritability, feeling your heartbeat, increased blood pressure, feeling or being sick, diarrhoea,, shivering or "		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
8	Oxynorm	Oxycodone hydrochloride	Possible side effects	Addition of text to read " These may be signs of a serious allergic reaction." Addition and Revision of text to read "and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and OxyNorm capsules'). Tell your doctor immediately if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms. Drug withdrawal When you stop taking OxyNorm capsules you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating. Drug withdrawal When you stop taking OxyNorm capsules you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating. How do I know if I am addicted? If you notice any of the following signs whilst taking OxyNorm capsules it could be a sign that you have become addicted. • You need to take the medicine for longer than advised by your prescriber; • You feel you need to use more than the recommended dose; • You are using the medicine for reasons other than prescribed; • When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again. If you notice any of these signs it is important you talk to your doctor." Addition of text to read under the heading Uncommon side effects "disorientation, palpitations, a feeling of lightheadedness, dizziness" Addition of text to read under the heading Frequency not known " • Dependence and addiction (see section 'How do I know if I am addicted? • Development of a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea"	20/05/2022	kama

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
9	Simbrinza	Brinzolamide / Brimonidine tartrate	Warnings and precautions	Revision of text to read "Simbrinza contains brinzolamide, a sulphonamide. Hypersensitivity reactions reported with sulphonamide derivatives, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), can occur in patients receiving Simbrinza as it is absorbed systemically. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs of serious reactions or hypersensitivity occur, use of this product should be discontinued immediately"	17/07/2022	Novartis
			Adverse Drug Reaction	Addition of subheading "Adverse drug reactions from spontaneous reports and literature cases (frequency not known)" Addition of text "The following adverse drug reactions have been derived from post-marketing experience with Simbrinza via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, ADRs are presented in order of decreasing seriousness" Addition of subheading "Table 2 Adverse drug reactions from spontaneous reports and literature (frequency not known)" Insertion of table with two columns "system organ classification" and "adverse drug reaction" with text "Skin and subcutaneous tissue disorders" under system organ classification and " Stevens-Johnson syndrome (SJS), Toxic epidermal necrolysis (TEN)" under adverse drug reaction.		
10	Tartar Control Listerine	Thymol, Alcohol and Zinc chloride	Posology and method of administration.	Revision of text to read "Adults and children 12 years and over: Use 20 mL (approximately ¾ capful) full strength; rinse the teeth and gums and gargle for 30 seconds twice daily as an adjunct to usual oral hygiene. Do not swallow. Cold weather may cloud Tartar Control Listerine® Antiseptic; its antiseptic properties are not affected. Not recommended for children under 12 years of age. "	28/03/2022	Johnson and Johnson
			Special warnings and precautions for use.	Revision of text to read "Do not swallow (see section 4.9). Keep out of reach of children. If swallowed, patients should get medical help or contact a Poison Control Centre right away. Since Tartar Control Listerine® Antiseptic contains alcohol, this should be used with caution in patients with Sjogren's syndrome, dry mouth or burning mouth syndrome. Patients should stop use and ask a dentist if oral irritation or any new symptoms develop. Tartar Control Listerine® Antiseptic contains sodium benzoate and benzoic acid. Tartar Control Listerine® Antiseptic may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism. "		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
10	Tartar Control Listerine	Thymol, Alcohol and Zinc chloride	Fertility, pregnancy and lactation	Addition of text to read" There are no adequate and well-controlled studies in pregnant women. However, because with recommended use only small volumes of Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the pregnant woman or foetus. It is not known whether Tartar Control Listerine® Antiseptic is excreted in human breast milk. However, because with recommended use only small volumes Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the infant."	28/03/2022	Johnson and Johnson
			Effects on ability to drive and use machines	Addition of text to read " Tartar Control Listerine® Antiseptic is unlikely to affect the ability to drive and use machinery. Caution is advised before driving a vehicle or operating machinery until the effects of Tartar Control Listerine® Antiseptic are known. Amended package insert (Professional Information)"		
			Undesirable effects	Adverse reactions identified during postmarketing experience: Immune system disorders.Frequency unknown: hypersensitivity reactions (including anaphylactic reactions, angioedema, and urticaria) Nervous system disorders. Frequency unknown: ageusia, dysgeusia, headache. Respiratory, thoracic and mediastinal disorders. Frequency unknown: sneezing. Gastrointestinal disorders. Frequency unknown: abdominal discomfort, diarrhoea, nausea, vomiting, salivary gland enlargement.Skin and subcutaneous tissue disorders Frequency unknown: rash General disorders and administration site conditions. Frequency unknown: application site reactions (usually these consist of dry mouth, tingling or burning pain but sometimes can include bleeding, blisters, discolouration, swelling and ulceration) Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of Tartar Control. Listerine® Antiseptic is important. It allows continued monitoring of the benefit/risk balance of Tartar Control Listerine® Antiseptic. Health care providers are asked to report any suspected adverse Adverse Drug Reactions Reporting publications: https://www.sahpra.org.za/Publications/Index/8 For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).		

No.	Name of Drug	Active Ingredient(s)	Updated Section	Update	Date of Update	MAH
11	Travatan eye drop	Travoprost 40 µg/mL Eye Drops Solution	Dosage regimen and administration	Insertion of subtitle "Special Populations" Revision of text under subtitle Renal Impairment to read" •Travatan has been studied in patients with mild to severe renal impairment (creatine clearance as low as 14 mL/min). •No dosage adjustment is necessary in these patients" Revision of text under subtitle Hepatic impairment to read" •Travatan has been studied in patients with mild to severe hepatic impairment. •No dosage adjusment is necessary in these patients" Revision of text under subtitle Pediatric population to read" •The safety and efficacy of Travatan in children below the age of 2 months have not been established. No data are available."	4/7/2022	Novartis
			Adverse drug reactions	Revision of text to read"Adverse drug reactions from clinical trials (Table 1) are listed by MedDRA system organ class. Within each system organ class, the adverse drug reactions are ranked by frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse drug reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000)." Insertion of text " Adverse drug reactions" in Table 1 which describes Adverse drug reactions from clinical trials with Travatan Insertion of text" Adverse drug reactions" in Table 2 which describes Adverse drug reactions from spontaneous reports and literature(frequency not known)		
			Pregnancy, Lactation, Females and Males of Reproductive Potential	Revision of text under Pregnancy with subtitle Risk Summary to read"There are no adequate well-controlled studies in pregnant women to inform a drug- associated risk. Studies in rats and mice with subcutaneous (s.c.) administration of travoprost during organogenesis have shown reproductive toxicity at the dose of 20 times and 1 time, respectively, the maximum recommended ocular human dose (MROHD) based on body surface area (BSA). Travatan should not be used during pregnancy unless clearly necessary." Revision of text under Lactation with subtitle Risk Summary to read"There is a limited amount of data from the use of Travatan Eye Drops, Solution in breast-feeding women. It is not known whether travoprost/metabolites are transferred into human milk after topical ocular administration. An animal study has shown transfer excretion of travoprost and/or metabolites into breast milk following subcutaneous administration (see Animal data). The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Travatan and any potential adverse effects on the breast-fed child from Travatan."		