

dose to decrease interaction effect. **Pregnancy and Lactation:** Do not use in the first trimester and discontinue as soon as possible if pregnancy occurs. Contraindicated in second and third trimesters of pregnancy. Not recommended during lactation. **Side Effects:** Konverge Plus: *Common* ($\geq 1/100 < 1/10$): upper respiratory tract infection, nasopharyngitis, urinary tract infection, dizziness, headache, palpitations, hypotension, diarrhoea, nausea, constipation, muscle spasm, joint swelling, pollakiuria, asthenia, peripheral oedema, fatigue, blood creatinine increased, blood urea increased, blood uric acid increased. Olmesartan: *Common:* urinary tract infection, hypertriglyceridaemia, hyperuricaemia, dizziness, headache, cough, bronchitis, pharyngitis, rhinitis, diarrhoea, nausea, abdominal pain, dyspepsia, gastroenteritis, arthritis, back pain, skeletal pain, haematuria, peripheral oedema, fatigue, chest pain, influenza-like symptoms, pain, blood urea increased, hepatic enzymes increased, blood creatine phosphokinase increased. Amlodipine: *Very common:* oedema. *Common:* dizziness, headache, somnolence, visual disturbance palpitations, flushing, dyspnoea, nausea, abdominal pain, altered bowel habits, dyspepsia, muscle spasm, ankle swelling, asthenia, fatigue. Hydrochlorothiazide: *Very common* ($\geq 1/10$): hypertriglyceridaemia, hypercholesterinaemia, hyperuricaemia. *Common:* hypokalaemia, glycosuria, hypercalcaemia, hyperglycaemia, hypomagnesaemia, hyponatraemia, hypochloraemia, hyperamylasaemia, confusional state, dizziness, diarrhoea, nausea, constipation, abdominal pain, meteorism, gastric irritation, vomiting, blood creatinine increased, blood urea increased. For less frequent side effects see SmPC. **Pack Sizes:** Blister containing 28 film-coated tablets. **Legal Category:** POM. **Product Authorisation Numbers:** PA 865/19/1-5. **Product Authorisation Holder:** Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request from A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC. **Date of Preparation:** October 2020

Omesar 10, 20, 40 mg film-coated tablets (olmesartan medoxomil). Prescribing information Please consult the Summary of Product Characteristics (SPC) for full prescribing information. **Presentation:** Film-coated tablets containing 10 mg, 20 mg, 40 mg olmesartan medoxomil. Contains lactose monohydrate. **Uses:** Treatment of essential hypertension in adults. Treatment of hypertension in children and adolescents from 6 to less than 18 years of age. **Dosage:** Oral administration. Adults (18-65 years): Recommended starting dose 10 mg daily. If required the dose may be increased to 20 mg daily. Maximum daily dose is 40 mg. Elderly (65 years or over): No dose adjustment generally required. If up-titration to maximum dosage required, monitor blood pressure closely. Patients with renal and moderate hepatic impairment: Maximum daily dose is 20 mg. Not recommended in patients with severe hepatic impairment. Children and adolescents aged 6 to less than 18 years: As for adults. Daily dose should not exceed 20 mg in children < 35 kg. Safety and efficacy not established in children aged 1 to 5 years. Not recommended for children under 1 year of age. **Contra-indications:** Hypersensitivity to any component. Second or third trimesters of pregnancy. Patients with biliary obstruction. Concomitant use with aiskiren-containing products in patients with diabetes mellitus or renal impairment. **Warnings and Precautions:** Correct intravascular volume depletion before administering olmesartan medoxomil. In patients with other conditions associated with stimulation of renin-angiotensin-aldosterone system, possible side effects include acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. Increased risk of severe hypotension and renal insufficiency in patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney. Periodic monitoring of serum and potassium levels is recommended in patients with impaired renal function and kidney transplantation. Not recommended in patients with severe renal impairment or with severe hepatic impairment. Hyperkalaemia (which may be fatal), risk factors include diabetes, renal impairment, age (> 70 years), combination with medicines which increase potassium levels, potassium supplements, intercurrent events. Close monitoring of serum potassium in at risk patients is recommended. Combined use of ACE-inhibitors, angiotensin II receptor blockers or aiskiren is not recommended. If considered absolutely necessary, use under specialist supervision with frequent close monitoring of renal function, electrolytes and blood pressure. Do not use concomitantly in patients with diabetic nephropathy. Not recommended for combination use with lithium. Special caution is recommended in patients suffering from aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy. Not recommended in patients with primary aldosteronism. Sprue-like enteropathy reported in very rare cases, in absence of other etiologies immediately discontinue treatment. The blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than non-black patients. Do not initiate during pregnancy and change to alternative therapy, if appropriate, if pregnancy is planned or occurs during therapy. Excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Contains lactose. **Interactions:** Not recommended for concomitant use with ACE-inhibitors, angiotensin II receptor blockers, aiskiren, drugs affecting potassium levels, lithium. The blood pressure lowering effect of olmesartan medoxomil can be increased by concomitant use with other antihypertensive medications. Risk of acute renal failure with concomitant use of NSAID's and angiotensin II antagonists. Monitoring of renal function and regular hydration of the patient is recommended. Use with NSAID's can reduce the effect of olmesartan medoxomil. Coadministration of warfarin and digoxin had no significant effect on the pharmacokinetics of olmesartan, warfarin or digoxin. No clinically relevant interactions between olmesartan and drugs metabolised by cytochrome P450 enzymes 1A1/2, 2A6, 2C8/9, 2C19, 2D6 and 3A4 are expected. Consider administration at least 4 hours before colesvelam dose to decrease interaction effect. Interaction studies only performed in adults. Not known if interactions in children are similar. **Pregnancy and lactation:** Do not use in the first trimester and discontinue as soon as possible if pregnancy occurs during therapy. Contraindicated in second and third trimester of pregnancy. Not recommended during lactation, change to alternative therapy, if appropriate. **Side Effects:** Common ($\geq 1/100$ to <1/10): hypertriglyceridaemia, hyperuricaemia, dizziness, headache, bronchitis, pharyngitis, cough, rhinitis, gastroenteritis, diarrhoea, abdominal pain, nausea, dyspepsia, arthritis, back pain, skeletal pain, haematuria, urinary tract infection, pain, chest pain, peripheral oedema, influenza-like symptoms, fatigue, hepatic enzymes increased, blood urea increased, blood creatine phosphokinase increased. Uncommon ($\geq 1/1,000$ to <1/100): thrombocytopenia, anaphylactic reaction, vertigo, angina pectoris, vomiting, exanthema, allergic dermatitis, urticaria, rash, pruritus, myalgia, face oedema, asthenia, malaise. Please consult the SPC. **Legal Category:** POM. **Product Authorisation Numbers:** PA 865/11/1-3. **Product Authorisation Holder:** Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. For further information please contact: A. Menarini Pharmaceuticals Ireland Ltd., Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924. **Date of Preparation:** March 2019

Omesar Plus 20 mg/12.5 mg and 20 mg/25 mg film-coated tablets (olmesartan medoxomil and hydrochlorothiazide). Prescribing information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing 20 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide or 20 mg olmesartan medoxomil and 25 mg hydrochlorothiazide. Contains lactose. **Uses:** Treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil alone. **Dosage:** Adults and the elderly: Recommended starting dose 20 mg olmesartan medoxomil and

12.5 mg hydrochlorothiazide once daily in patients whose blood pressure is not adequately controlled on 20 mg olmesartan medoxomil alone. Monitoring advised in patients with mild to moderate renal impairment. Caution in patients with mild to moderate hepatic impairment. Contra-indicated in patients with severe renal impairment, severe hepatic impairment cholestasis or biliary obstruction. No data available on use in children and adolescents below 18 years. **Contra-indications:** Hypersensitivity to any component or to sulfonamide-derived substances. Severe renal impairment (creatinine clearance < 30 mL/min). Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia. Severe hepatic impairment, cholestasis and biliary obstructive disorders. Second or third trimesters of pregnancy. Concomitant use with aiskiren-containing products in patients with diabetes mellitus or renal impairment. **Warnings and precautions:** Correct intravascular volume depletion before administering. Other conditions associated with stimulation of renin-angiotensin-aldosterone system. Renovascular hypertension. Periodic monitoring of serum potassium, creatinine and uric acid levels is recommended in patients with mild to moderate renal impairment. Combined use of ACEinhibitors, angiotensin II receptor blockers or aiskiren is not recommended. If considered absolutely necessary, use under specialist supervision with frequent close monitoring of renal function, electrolytes and blood pressure. Do not use concomitantly in patients with diabetic nephropathy. Care in mild to moderate hepatic impairment. Aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy. Not recommended in patients with primary aldosteronism. Metabolic and endocrine effects (eg in diabetic patients). Fluid or electrolyte imbalance. Monitoring of serum potassium in patients at risk of hyperkalaemia is recommended. Not recommended with lithium. Sprue-like enteropathy reported in very rare cases, in absence of other etiologies immediately discontinue treatment. Hydrochlorothiazide may cause choroidal effusion with visual field defect, acute myopia and secondary angle-closure glaucoma, if occurs discontinue hydrochlorothiazide treatment as rapidly as possible. Increased risk of non-melanoma skin cancer with increasing cumulative dose of HCTZ. Patients should be advised to regularly check skin for any new lesions, limit sun and UV ray exposure and use preventative measure where possible, e.g. sun protection. Suspicious skin lesions should be examined promptly. Reconsider use of HCTZ in patients with previous NMSC. The blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than non-black patients. May cause a positive result in an anti-doping test. As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Contains lactose. Not recommended with medicinal products affecting potassium levels. Do not initiate during pregnancy and change to alternative therapy, if appropriate, if pregnancy is planned or occurs during therapy. **Pregnancy and lactation:** Do not use in the first trimester and discontinue as soon as possible if pregnancy occurs during therapy. Contraindicated in second and third trimester of pregnancy. Not recommended during lactation, change to alternative therapy, if appropriate. **Interactions:** Not recommended for concomitant use with ACE-inhibitors, angiotensin II receptor blockers, aiskiren, lithium, drugs affecting potassium levels. The blood pressure lowering effect of olmesartan medoxomil can be increased by concomitant use with other antihypertensive medications. Risk of acute renal failure with concomitant use of NSAID's and angiotensin receptor II antagonists. Monitoring of renal function and regular hydration of the patient is recommended. Use with NSAID's can reduce the effect of olmesartan medoxomil. Coadministration of warfarin and digoxin had no significant effect on the pharmacokinetics of olmesartan, warfarin or digoxin. No clinically relevant interactions between olmesartan and drugs metabolised by cytochrome P450 enzymes 1A1/2, 2A6, 2C8/9, 2C19, 2D6 and 3A4 are expected. Caution if used concomitantly with baclofen, calcium salts, cholestyramine and colestipol resins, digitalis glycosides, medicinal products affected by serum potassium disturbances non-depolarizing skeletal muscle relaxants (eg tubocurarine), anticholinergic agents (eg atropine, biperiden), antidiabetic medicinal products (oral agents and insulin), metformin, beta-blockers and diazoxide, pressor amines (eg noradrenaline), medicinal products used in the treatment of gout (probenecid, sulfipyrazone and allopurinol), amantadine, cytotoxic agents (eg cyclophosphamide, methotrexate), salicylates, methylodpa, cyclosporine, tetracyclines. Concomitant use to be taken into account with amifostine, alcohol, barbiturates, narcotics or antidepressants. Consider administration at least 4 hours before colesvelam dose to decrease interaction effect. For further information see SmPC. **Side effects: Fixed dose combination:** Common: dizziness/light-headedness, headache, fatigue, asthenia, peripheral oedema, chest pain. Uncommon: hyperuricaemia, hypertriglyceridaemia, hypercholesterolaemia, syncope, postural dizziness, somnolence, palpitations, vertigo, hypotension, orthostatic hypotension, cough, diarrhoea, nausea, vomiting, dyspepsia, abdominal pain, rash, eczema, myalgia, muscle spasm, back pain, arthralgia, pain in extremity, haematuria, erectile dysfunction, weakness, blood potassium decreased, blood potassium increased, blood calcium increased, blood urea increased, blood lipids increased, blood creatinine increased, blood glucose increased, gamma glutamyl transferase increased, alanine aminotransferase increased, aspartate aminotransferase increased. For side effects which are rare or whose frequency is unknown see SmPC. *Olmesartan:* Common: hypertriglyceridaemia, hyperuricaemia, dizziness/light-headedness, headache, increased blood creatine phosphokinase, bronchitis, cough, pharyngitis, rhinitis, abdominal pain, diarrhoea, dyspepsia, gastroenteritis, nausea, arthritis, back pain, skeletal pain, haematuria, urinary tract infection, influenza-like symptoms, chest pain, fatigue, pain, peripheral oedema, blood urea increased, hepatic enzymes increased. Uncommon: thrombocytopenia, anaphylactic reactions, vertigo, angina pectoris, vomiting, allergic dermatitis, exanthem, pruritus, rash, urticaria, myalgia, asthenia, face oedema, malaise. For side effects which are rare or whose frequency is unknown see SmPC. *Hydrochlorothiazide:* Very common: hypercholesterolaemia, hypertriglyceridaemia, hyperuricaemia. Common: hyperglycaemia, glykosuria, hyponatraemia, hyperamylasaemia, hypomagnesaemia, hypochloraemia, hypokalaemia, hypercalcaemia, dizziness/light-headedness, confusional state, abdominal pain, diarrhoea, gastric irritation, constipation, meteorism, nausea, vomiting, blood creatinine increased, blood urea increased. Uncommon: anaphylactic reactions, anorexia, loss of appetite, worsening of pre-existing myopia, orthostatic hypotension, respiratory distress, erythema, photosensitivity reactions, pruritus, purpura, rash, urticaria, erectile dysfunction. For side effects which are rare, very rare or whose frequency is unknown see SmPC. **Pack Size:** 28 film-coated tablets. **Legal Category:** POM. **Marketing Authorisation Number:** PA 865/14/1-2. **Marketing Authorisation Holder:** Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Co. Dublin A96 T924 or may be found in the SmPC. **Date of preparation:** August 2020

Omesar Plus 40 mg/12.5 mg and 40 mg/25 mg film-coated tablets (olmesartan medoxomil and hydrochlorothiazide). Prescribing information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide or 40 mg olmesartan medoxomil and 25 mg hydrochlorothiazide. Contains lactose. **Uses:** Treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil 40 mg alone. **Dosage:** Adults: Recommended dose 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide once daily in patients whose blood pressure is not adequately controlled on 40 mg olmesartan medoxomil alone. Recommended dose 40 mg olmesartan medoxomil and 25 mg hydrochlorothiazide once daily in patients whose blood pressure is not

adequately controlled on 40 mg olmesartan medoxomil and 12.5 mg hydrochlorothiazide fixed dose combination. Monitor blood pressure closely in the elderly. Contra-indicated in all stages of renal impairment. Caution in patients with mild hepatic impairment, monitor blood pressure and renal function closely. Do not use in patients with moderate and severe hepatic impairment, cholestasis or biliary obstruction. No data available on use in children and adolescents below 18 years. **Contra-indications:** Hypersensitivity to the active substance or any of the excipients. Renal impairment. Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia. Moderate and severe hepatic impairment, cholestasis and biliary obstructive disorders. Second or third trimester of pregnancy. Concomitant use with aiskiren-containing products in patients with diabetes mellitus or renal impairment. **Warnings and precautions:** Symptomatic hypotension in patients who are volume and/or sodium depleted. Correct intravascular volume depletion before administering. Other conditions associated with stimulation of renin-angiotensin-aldosterone system. Renovascular hypertension. Not recommended in all stages of renal impairment. No experience in patients with a recent kidney transplant. Combined use of ACE-inhibitors, angiotensin II receptor blockers or aiskiren is not recommended. If considered absolutely necessary, use under specialist supervision with frequent close monitoring of renal function, electrolytes and blood pressure. Do not use concomitantly in patients with diabetic nephropathy. Contra-indicated in moderate and severe hepatic impairment, cholestasis and biliary obstruction. Care in mild hepatic impairment. Special caution with aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy. Not recommended in patients with primary aldosteronism. May cause hyperglycaemia, raised triglyceride and cholesterol levels and hyperuricaemia. Periodic determination of serum electrolytes should be performed at regular intervals. Not recommended with lithium. Sprue-like enteropathy reported in very rare cases, in absence of other etiologies immediately discontinue treatment. Hydrochlorothiazide may cause choroidal effusion with visual field defect, acute myopia and secondary angle-closure glaucoma, if occurs discontinue hydrochlorothiazide treatment as rapidly as possible. Increased risk of non-melanoma skin cancer with increasing cumulative dose of HCTZ. Patients should be advised to regularly check skin for any new lesions, limit sun and UV ray exposure and use preventative measure where possible, e.g. sun protection. Suspicious skin lesions should be examined promptly. Reconsider use of HCTZ in patients with previous NMSC. The blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than non-black patients. May cause a positive result in an anti-doping test. Do not initiate during pregnancy and change to alternative therapy, if appropriate, if pregnancy is planned or occurs during therapy. As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Hypersensitivity reactions to hydrochlorothiazide. Exacerbation or activation of systemic lupus erythematosus. Contains lactose. **Interactions:** Not recommended for concomitant use with ACE-inhibitors, angiotensin II receptor blockers, aiskiren, lithium, drugs affecting potassium levels. The blood pressure lowering effect of olmesartan medoxomil can be increased by concomitant use with other antihypertensive medications. Risk of acute renal failure with concomitant use of NSAID's and angiotensin II receptor antagonists. Monitoring of renal function and regular hydration of the patient is recommended. Use with NSAID's can reduce the effect of olmesartan medoxomil. Coadministration of warfarin and digoxin had no significant effect on the pharmacokinetics of warfarin or digoxin. No clinically relevant interactions between olmesartan and drugs metabolised by cytochrome P450 enzymes 1A1/2, 2A6, 2C8/9, 2C19, 2D6 and 3A4 are expected. Caution if used concomitantly with baclofen, calcium salts, cholestyramine and colestipol resins, digitalis glycosides, medicinal products affected by serum potassium disturbances, nondepolarizing skeletal muscle relaxants (e.g. tubocurarine), anticholinergic agents (e.g. atropine, biperiden), antidiabetic medicinal products (oral agents and insulin), metformin, beta-blockers and diazoxide, pressor amines (e.g. noradrenaline), medicinal products used in the treatment of gout (probenecid, sulfipyrazone and allopurinol), amantadine, cytotoxic agents (e.g. cyclophosphamide, methotrexate), salicylates, methylodpa, cyclosporine, tetracyclines. Concomitant use to be taken into account with amifostine, alcohol, barbiturates, narcotics or antidepressants. Consider administration at least 4 hours before colesvelam dose to decrease interaction effect. For further information see SmPC. **Pregnancy and lactation:** Do not use in the first trimester and discontinue as soon as possible if pregnancy occurs during therapy. Contraindicated in second and third trimester of pregnancy. Not recommended during lactation, change to alternative therapy, if appropriate. **Side effects: Fixed dose combination:** Common: dizziness/light-headedness, headache, asthenia, chest pain, fatigue, peripheral oedema. Uncommon: hypercholesterolaemia, hypertriglyceridaemia, hyperuricaemia, postural dizziness, somnolence, syncope, vertigo, palpitations, hypotension, orthostatic hypotension, cough, abdominal pain, diarrhoea, dyspepsia, nausea, vomiting, eczema, rash, arthralgia, back pain, muscle spasm, myalgia, pain in extremity, haematuria, erectile dysfunction, weakness, alanine aminotransferase increased, aspartate aminotransferase increased, blood calcium increased, blood creatinine increased, blood glucose increased, blood lipids increased, blood potassium decreased, blood potassium increased, blood urea increased, gamma glutamyl transferase increased. For side effects which are rare see SmPC. *Olmesartan:* Common: hypertriglyceridaemia, hyperuricaemia, dizziness/light-headedness, headache, bronchitis, cough, pharyngitis, rhinitis, abdominal pain, diarrhoea, dyspepsia, gastroenteritis, nausea, arthritis, back pain, skeletal pain, haematuria, urinary tract infection, influenza-like symptoms, pain, peripheral oedema, blood urea increased, hepatic enzymes increased. Uncommon: thrombocytopenia, anaphylactic reactions, vertigo, angina pectoris, vomiting, allergic dermatitis, exanthem, pruritus, rash, urticaria, myalgia, asthenia, face oedema, malaise. For side effects which are rare see SmPC. *Hydrochlorothiazide:* Very common: hypercholesterolaemia, hypertriglyceridaemia. Common: glykosuria, hypercalcaemia, hyperglycaemia, hypochloraemia, hypokalaemia, hypercalcaemia, hypomagnesaemia, hyponatraemia, hyperamylasaemia, confusional state, dizziness/ lightheadedness, abdominal pain, constipation, diarrhoea, gastric irritation, meteorism, nausea, vomiting, blood creatinine increased, blood urea increased. Uncommon: anaphylactic reactions, anorexia, loss of appetite, worsening of pre-existing myopia, orthostatic hypotension, respiratory distress, erythema, photosensitivity reactions, pruritus, purpura, rash, urticaria, erectile dysfunction. For side effects which are rare, very rare or whose frequency is unknown see SmPC. **Pack Size:** 28 film-coated tablets. **Legal Category:** POM. **Marketing Authorisation Holder:** Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC. **Date of preparation:** August 2020

Date of item: January 2021. IR-KON-01-2021.



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	Olmesartan	Amlodipine	HCTZ	Therapeutic Indications
OMESAR Olmesartan Medoxomil	1. 10 mg	None	None	Treatment of essential hypertension in adults.
	2. 20 mg	None	None	
	3. 40 mg	None	None	
OMESAR PLUS Olmesartan Medoxomil/HCTZ	4. 20 mg	None	12.5 mg	Treatment of essential hypertension.
	5. 20 mg	None	25 mg	Olmesar Plus fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil alone.
	6. 40 mg	None	12.5 mg	Treatment of essential hypertension.
	7. 40 mg	None	25 mg	Olmesartan and hydrochlorothiazide 40 mg/12.5 mg and 40 mg/25 mg fixed dose combinations are indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil 40 mg alone.
KONVERGE Olmesartan Medoxomil/Amlodipine	8. 20 mg	5 mg	None	Treatment of essential hypertension.
	9. 40 mg	5 mg	None	Konverge is indicated in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy
	10. 40 mg	10 mg	None	
KONVERGE PLUS Olmesartan Medoxomil/Amlodipine/HCTZ	11. 20 mg	5 mg	12.5 mg	Treatment of essential hypertension.
	12. 40 mg	5 mg	12.5 mg	Add-on therapy Konverge Plus is indicated in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.
	13. 40 mg	10 mg	12.5 mg	Substitution therapy Konverge Plus is indicated as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine).
	14. 40 mg	5 mg	25 mg	
	15. 40 mg	10 mg	25 mg	

References:

1. Omesar Summary of Product Characteristics February 2019. 2. Omesar Plus 20 mg/12.5 mg & 20 mg/25 mg Summary of Product Characteristics July 2020. 3. Omesar Plus 40 mg/12.5 mg & 40 mg/25 mg Summary of Product Characteristics July 2020. 4. Konverge Summary of Product Characteristics December 2020. 5. Konverge Plus Summary of Product Characteristics October 2020.

Konverge 20 mg/5 mg, 40 mg/5 mg and 40 mg/10 mg film-coated tablets (olmesartan medoxomil/amlodipine) Prescribing information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing 20 mg of olmesartan medoxomil and 5 mg of amlodipine (as amlodipine besilate) or 40 mg of olmesartan medoxomil and 5 mg of amlodipine (as amlodipine besilate) or 40 mg of olmesartan medoxomil and 10 mg of amlodipine (as amlodipine besilate). **Uses:** Treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on olmesartan medoxomil or amlodipine monotherapy. **Dosage:** Oral administration. Adults (18-65 years): Recommended dose is 1 tablet daily. Elderly (65 years or over): No dose adjustment generally required but increase dosage with care. If up-titration to maximum dosage required, monitor blood pressure closely. Severe renal impairment: Not recommended. Patients with mild to moderate renal impairment: Maximum daily dose of olmesartan medoxomil is 20 mg. Monitor potassium levels and creatinine. Severe hepatic impairment: Contraindicated. Patients with mild to moderate hepatic impairment: Use with caution. Starting dose 10 mg olmesartan medoxomil daily. Maximum daily dose of olmesartan medoxomil is 20 mg. Monitor blood pressure and renal function. Initiate amlodipine at the lowest dose and titrate slowly. Children and adolescents under 18 years: Not recommended. **Contraindications:** Hypersensitivity to any component. Second or third trimesters of pregnancy. Patients with severe hepatic insufficiency or biliary obstruction, severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle, haemodynamically unstable heart failure after acute myocardial infarction. Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment. **Warnings and Precautions:** Correct intravascular volume depletion before administering olmesartan medoxomil or maintain close medical supervision. In patients with other conditions associated with stimulation of renin-angiotensin-aldosterone system, possible side effects include acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. Increased risk of severe hypotension and renal insufficiency in patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney. Periodic monitoring of serum and potassium levels is recommended in patients with impaired renal function and kidney transplantation. Not recommended in patients with severe renal impairment. Combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is not recommended. If considered absolutely necessary, use under specialist supervision with frequent close monitoring of renal function, electrolytes and blood pressure. Do not use concomitantly in patients with diabetic nephropathy. Take care in mild to moderate hepatic impairment. Initiate amlodipine at the lowest dose and use with caution for initial treatment and when increasing dose. Hyperkalaemia, risk factors include renal impairment, and/or heart failure. Monitoring of serum potassium in patients at risk of hyperkalaemia is recommended. Concomitant use of potassium containing and sparing products should be undertaken with caution and potassium levels monitored frequently. Not recommended for combination use with lithium. Special caution is recommended in patients suffering from aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy. Not recommended in patients with primary aldosteronism. Changes in renal function in susceptible individuals with heart failure. In patients with severe heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with ACE inhibitors and angiotensin receptor antagonists has been associated with oliguria and/or progressive azotaemia and (rarely) with acute renal failure and/or death. Use with caution in patients with heart failure. Sprue-like enteropathy reported in very rare cases, in absence of other etiologies immediately discontinue treatment. The blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than non-black patients. Increase dose with care in the elderly. Do not initiate during pregnancy. Discontinue as soon as possible if pregnancy occurs during therapy. Excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. **Interactions:** The blood pressure lowering effect of Konverge can be increased by concomitant use with other antihypertensive medicinal products. Olmesartan medoxomil component: Not recommended for concomitant use with ACE-inhibitors, angiotensin II receptor blockers, aliskiren, drugs affecting potassium levels, lithium. Caution with concomitant use of NSAIDs and angiotensin II antagonists. Amlodipine component: Caution with concomitant use with CYP3A4 inhibitors and CYP3A4 inducers. Dantrolene (infusion): avoid co-administration in patients susceptible to malignant hyperthermia and in its management. Limit dose of simvastatin in patients on amlodipine to 20 mg daily. Consider administration at least 4 hours before colesvelam dose to decrease interaction effect. Tacrolimus: monitor blood levels and adjust dose as appropriate. Ciclosporin: monitor trough levels and reduce dose as necessary. mTOR inhibitors are CYP3A substrates. Amlodipine is a weak CYP3A inhibitor. With concomitant use of mTOR inhibitors, amlodipine may increase exposure of mTOR inhibitors. **Pregnancy and Lactation:** Do not use in the first trimester and discontinue as soon as possible if pregnancy occurs during therapy. Contraindicated in second and third trimesters of pregnancy. Not recommended during lactation, change to alternative therapy, if appropriate. **Side Effects:** *Olmesartan/amlodipine combination:* Common: dizziness, headache, fatigue, oedema, peripheral oedema, pitting oedema. Uncommon: hyperkalaemia, libido decreased, hypoaesthesia, lethargy, paraesthesia, postural dizziness, vertigo, palpitations, tachycardia, hypotension, orthostatic hypotension, cough, dyspnoea, constipation, diarrhoea, dry mouth, dyspepsia, nausea, upper abdominal pain, vomiting, rash, back pain, muscle spasm, pain in extremity, pollakiuria, erectile dysfunction/impotence, asthenia, blood creatinine increased, blood potassium decreased, blood uric acid increased, gamma glutamyl transferase increased. Rare: allergic reaction/drug hypersensitivity, syncope, flushing, urticaria, face oedema. *Olmesartan:* Common: hypertriglyceridaemia, hyperuricaemia, dizziness, headache, bronchitis, cough, pharyngitis, rhinitis, abdominal pain, diarrhoea, dyspepsia, gastroenteritis, nausea, hepatic enzyme increased, arthritis, back pain, skeletal pain, haematuria, urinary tract infection, chest pain, fatigue, influenza-like symptoms, pain, peripheral oedema, blood creatine phosphokinase increased, blood urea increased. Uncommon: thrombocytopenia, anaphylactic reaction, vertigo, angina pectoris, vomiting, allergic dermatitis, exanthema, pruritus, rash, urticaria, myalgia, asthenia, face oedema, malaise. Rare: hyperkalaemia, hypotension, angioneurotic oedema, muscle spasm, acute renal failure, renal insufficiency, lethargy, blood creatinine increased. *Amlodipine:* Very Common: oedema. Common: dizziness, headache, somnolence, visual disturbance, palpitations, flushing, dyspnoea, abdominal pain, altered bowel habits, dyspepsia, nausea, ankle swelling, muscle spasm, asthenia, fatigue. Uncommon: depression, insomnia, irritability, mood changes, dysgeusia, hypoaesthesia, paraesthesia, sleep disorder, syncope, tremor, tinnitus, angina pectoris, arrhythmia, hypotension, cough, rhinitis, altered bowel habits, dry mouth, vomiting, alopecia, exanthema, hyperhidrosis, pruritus, purpura, rash, skin discoloration, urticaria, arthralgia, back pain, myalgia, increased urinary frequency, micturition disorder, nocturia, erectile dysfunction/impotence, gynecomastia, chest pain, malaise, pain, increase or decrease in weight. Rare: confusion. Very rare: leukocytopenia, thrombocytopenia, allergic reaction /drug hypersensitivity, hyperglycaemia, hypertonia, peripheral neuropathy, myocardial infarction, vasculitis, gastritis, gingival hyperplasia, pancreatitis, hepatic

enzymes increased, hepatitis, jaundice, angioneurotic oedema, erythema multiforme, exfoliative dermatitis, photosensitivity, Quincke oedema, Stevens-Johnson syndrome. Please consult the Summary of Product Characteristics for a full list of side effects. **Pack Sizes:** Blister containing 28 film-coated tablets. **Legal Category:** POM. **Product Authorisation Numbers:** PA 865/17/1-3. **Product Authorisation Holder:** Menarini International Operations Luxembourg S.A, 1 Avenue de la Gare, L-1611 Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request from A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC. **Date of Preparation:** December 2020.

Konverge Plus 20 mg/5 mg/12.5 mg, 40 mg/5 mg/12.5 mg, 40 mg/10 mg/12.5 mg, 40 mg/5 mg/25 mg and 40 mg/10 mg/25 mg film-coated tablets (olmesartan medoxomil /amlodipine [as amlodipine besilate]/hydrochlorothiazide) Prescribing information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information. **Presentation:** Film-coated tablets containing: 20 mg olmesartan medoxomil, 5 mg amlodipine, 12.5 mg hydrochlorothiazide or 40 mg olmesartan medoxomil, 5 mg amlodipine, 12.5 mg hydrochlorothiazide or 40 mg olmesartan medoxomil, 10 mg amlodipine, 12.5 mg hydrochlorothiazide or 40 mg olmesartan medoxomil, 5 mg amlodipine, 25 mg hydrochlorothiazide. **Uses:** Treatment of essential hypertension. Indicated as add-on therapy in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation. Also as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of olmesartan medoxomil, amlodipine and hydrochlorothiazide, taken as a dual-component (olmesartan medoxomil and amlodipine or olmesartan medoxomil and hydrochlorothiazide) and a single-component formulation (hydrochlorothiazide or amlodipine). **Dosage:** Oral administration. Adults (18-65 years): Recommended dose is 1 tablet daily. Add-on therapy: administer in patients whose blood pressure is not adequately controlled on olmesartan medoxomil and amlodipine taken as dual-component combination. Step-wise titration of the dosage of the individual components recommended before changing to the triple-component combination. When clinically appropriate, direct change from dual-component combination to triple-component combination may be considered. Substitution therapy: dose to be based on the doses of the individual components of combination at time of switching. Maximum daily dose of 40 mg/10 mg/25 mg. Elderly (65 years or over): Caution, monitor blood pressure frequently especially at maximum dose. Increase dosage with care. Extreme caution, including more frequent monitoring of blood pressure, recommended in patients aged 75 or older. Patients with mild to moderate renal impairment: Maximum dose 20 mg/5 mg/12.5 mg and monitor potassium and creatinine levels. Caution in patients with mild to moderate hepatic impairment; maximum daily dose 20 mg/5 mg/12.5 mg; monitor blood pressure and renal function closely. Use with caution in patients with impaired liver function. Initiate amlodipine at the lowest dose and titrate slowly. Contra-indicated in severe hepatic impairment. Children and adolescents under 18 years: Not recommended. **Contra-indications:** Hypersensitivity to any component, to dihydropyridine derivatives or to sulfonamide-derived substances. Severe renal impairment. Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia. Severe hepatic insufficiency, cholestasis or biliary obstruction. Second or third trimesters of pregnancy. Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment. Severe hypotension, shock (including cardiogenic shock), obstruction of the outflow tract of the left ventricle, haemodynamically unstable heart failure after acute myocardial infarction. **Warnings and Precautions:** Correct intravascular volume depletion before administering Konverge Plus or maintain close medical supervision. In patients with other conditions associated with stimulation of renin-angiotensin-aldosterone system, possible side effects include acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. Increased risk of severe hypotension and renal insufficiency in patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney. Periodic monitoring of serum and potassium levels is recommended in patients with impaired renal function and kidney transplantation. Combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is not recommended. If considered absolutely necessary, use under specialist supervision with frequent close monitoring of renal function, electrolytes and blood pressure. Do not use concomitantly in patients with diabetic nephropathy. Special caution in patients with aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy. Not recommended in patients with primary aldosteronism. May impair glucose tolerance. In diabetic patients dosage adjustments of insulin or oral hypoglycaemic agents may be required. Increases in cholesterol and triglyceride levels. Thiazides may precipitate hyperuricaemia or frank gout. Periodic determination of serum electrolytes should be performed. Can cause fluid or electrolyte imbalance (including hypokalaemia, hyponatraemia and hypochloroemic alkalosis). Risk of hypokalaemia with cirrhosis of the liver, brisk diuresis, inadequate oral intake of electrolytes, concomitant therapy with corticosteroids or ACTH. Hyperkalaemia, risk factors include renal impairment, and/or heart failure. Close monitoring of serum potassium in patients at risk of hyperkalaemia is recommended. Concomitant use of potassium containing and sparing products should be undertaken with caution and potassium levels monitored frequently. May cause intermittent and slight elevation of serum calcium. Discontinue before carrying out tests for parathyroid function. May increase urinary excretion of magnesium. Dilutional hyponatraemia may occur in oedematous patients in hot weather. Not recommended for combination use with lithium. Changes in renal function in susceptible individuals with heart failure. Amlodipine associated with increased reports of pulmonary oedema. Treat patients with heart failure with caution. Use amlodipine with caution in patients with congestive heart failure. Sprue-like enteropathy reported in very rare cases, in absence of other etiologies immediately discontinue treatment. Hydrochlorothiazide, can cause an idiosyncratic reaction, resulting in choroidal effusion with visual field defect, acute transient myopia and acute angle-closure glaucoma. Do not initiate during pregnancy. Discontinue as soon as possible if pregnancy occurs. Increase dosage with care in the elderly. Photosensitivity reactions have been reported with thiazide diuretics. Increased risk of non-melanoma skin cancer with increasing cumulative dose of HCTZ. Patients should be advised to regularly check skin for any new lesions, limit sun and UV ray exposure and use preventative measure where possible, e.g. sun protection. Suspicious skin lesions should be examined promptly. Reconsider use of HCTZ in patients with previous NMSC. Excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma. Exacerbation or activation of systemic lupus erythematosus with the use of thiazides. The blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than non-black patients. **Interactions:** Not recommended for concomitant use with ACE-inhibitors, angiotensin II receptor blockers, aliskiren, lithium, drugs affecting potassium levels. Caution with baclofen, NSAIDs, amifostine, other hypertensive agents, alcohol, barbiturates, narcotics, antidepressants, CYP3A4 inhibitors, CYP3A4 inducers, calcium salts, cholestyramine and colestipol, digitalis glycosides, non-depolarizing skeletal muscle relaxants, anticholinergic agents, antidiabetic medicinal products, beta-blockers and diazoxide, pressor amines, medicinal products used in the treatment of gout, amantadine, cytotoxic agents, salicylates, methyldopa, tetracyclines, grapefruit juice, dantrolene, simvastatin, tacrolimus, mechanistic target of rapamycin (mTOR) inhibitors, cyclosporine. Consider administration at least 4 hours before colesvelam