Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Konverge Plus

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Konverge Plus contains
The active substances are olmesartan medoxomil, amlodipine (as amlodipine besilate) and hydrochlorothiazide.

Each film-coated tablet contains 40 mg olmesartan medoxomil, 5 mg amlodipine (as amlodipine besilate) and 12.5 mg hydrochlorothiazide.
The other ingredients are:
Tablet core: pregelatinized maize starch, silicified microcrystalline cellulose (microcrystalline cellulose and silica colloidal anhydrous), croscarmellose sodium, magnesium stearate
Film coat: polyvinyl alcohol, macrogol 3350, talc, titanium dioxide (E 171) and yellow iron oxide (E 172).

What Konverge Plus looks like and contents of the pack
Konverge Plus 40 mg/5 mg/12.5 mg film-coated tablets of 9.5 mm are light yellow, round with C53 debossed on one side.

Konverge Plus film-coated tablets are available in blister packs 28 film-coated tablets.

The Parallel Product Authorisation Holder is:
LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:
Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturers are:
DAIICHI SANKYO EUROPE GmbH, 81366 Munich, Germany

Berlin-Chemie AG, 12489 Berlin, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Amelior plus HCT 40 mg/5 mg/12.5 mg
Belgium: Forzaten/HCT 40 mg/5 mg/12.5 mg
Bulgaria: Tespadan HCT 40 mg/5 mg/12.5 mg
Cyprus: Orizal plus 40 mg/5 mg/12.5 mg
Czech Republic: Sintonyn Combi 40 mg/5 mg/12.5mg
Denmark: Alea COMP 40 mg/5 mg/12.5 mg
Estonia: Sanoral HCT 40 mg/5 mg/12.5 mg
Finland: Alea COMP 40 mg/5 mg/12.5 mg
France: TRIAXELER 40 mg/5 mg/12.5 mg
Germany: Vocado HCT 40 mg/5 mg/12.5 mg
Greece: Orizal plus 40 mg/5 mg/12.5 mg
Hungary: Duactan HCT 40 mg/5 mg/12.5 mg
Iceland: Alea COMP 40 mg/5 mg/12.5 mg
Ireland: Konverge Plus 40 mg/5 mg/12.5 mg
Italy: Trivis 40 mg/5 mg/12.5 mg
Latvia: Sanoral HCT 40 mg/5 mg/12.5 mg
Lithuania: Sanoral HCT 40 mg/5 mg/12.5 mg
Luxembourg: Forzaten/HCT 40 mg/5 mg/12.5 mg
The Netherlands: Belfor HCT 40 mg/5 mg/12.5 mg
Malta: Konverge Plus 40 mg/5 mg/12.5 mg
Norway: Alea COMP 40 mg/5 mg/12.5 mg
Poland: Elestar HCT 40 mg/5 mg/12.5 mg
Portugal: Zolnor HCT 40 mg/5 mg/12.5 mg
Romania: Inovum HCT 40 mg/5 mg/12.5 mg
Slovak Republic: Folgan HCT 40 mg/5 mg/12.5 mg
Slovenia: Olectan HCT 40 mg/5 mg/12.5 mg
Spain: Balzak plus 40 mg/5 mg/12.5 mg

Konverge Plus is a registered trademark of DAIICHI SANKYO COMPANY, LIMITED.

POM PPA1562/174/002

Revision date: 03/10/2016

Konverge Plus® 40 mg/5 mg/12.5 mg film-coated tablets

Ref: 174/002/031016/1/F

(olmesartan medoxomil/amlodipine/hydrochlorothiazide)

Package Leaflet: Information for the patient

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Konverge Plus is and what it is used for
2 What you need to know before you take Konverge Plus
3 How to take Konverge Plus
4 Possible side effects
5 How to store Konverge Plus
6 Contents of the pack and other information

1 What Konverge Plus is and what it is used for

Konverge Plus contains three active substances called olmesartan medoxomil, amlodipine (as amlodipine besilate) and hydrochlorothiazide. All three substances help to control high blood pressure.
- Olmesartan medoxomil belongs to a group of medicines called “angiotensin-II receptor antagonists”, which lowers blood pressure by relaxing the blood vessels.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine also lowers blood pressure by relaxing blood vessels.
- Hydrochlorothiazide is one of a group of medicines called thiazide diuretics (“water tablets”). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

The actions of these substances contribute to decrease your blood pressure.

Konverge Plus is used for the treatment of high blood pressure:
- in adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as fixed-dose combination, or
- in patients, who are already taking a fixed-dose combination of olmesartan medoxomil and hydrochlorothiazide plus the amlodipine as a single tablet or a fixed-dose combination of olmesartan medoxomil and amlodipine plus hydrochlorothiazide as a single tablet.

2 What you need to know before you take Konverge Plus

Do not take Konverge Plus if:
- you are allergic to olmesartan medoxomil, to amlodipine or a special group of calcium channel blockers (the dihydropyridines) to hydrochlorothiazide or to substances similar to hydrochlorothiazide (sulfonamides) or to any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic talk to your doctor before taking Konverge Plus.
- you have severe kidney problems.
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- you have low potassium, low sodium, high calcium or high uric acid (with symptoms of gout or kidney stones) levels in your blood that have not got better when treated.
- you are more than 3 months pregnant. (It is also better to avoid Konverge Plus in early pregnancy - see section “Pregnancy and breast-feeding”.)
- you have severe liver problems, if bile secretion is impaired or drainage of bile from the gall bladder is blocked (e. g. by gallstones), or if you are jaundiced (yellowing of the skin and eyes).
- you have a poor blood supply to your tissues with symptoms such as low blood pressure, low pulse, fast heartbeat or shock (including cardiogenic shock, which means shock due to severe heart troubles).
- you have very low blood pressure.
- the blood flow from your heart is slow or blocked. This may happen if the blood vessel or valve that takes blood away from your heart becomes narrow (aortic stenosis).
- you have a low heart output after a heart attack (acute myocardial infarction). Low heart output may make you feel short of breath or have swelling in your feet and ankles.

Do not take Konverge Plus if any of the above applies to you.

Warnings and precautions
Talk to your doctor or pharmacist before using Konverge Plus.

Tell your doctor if you are taking any of the following medicines used to treat high blood pressure:
- an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems,
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Konverge Plus if”

Tell your doctor if you have any of the following health problems:
- Kidney problems or a kidney transplant.
- Liver disease.
- Heart failure or problems with your heart valves or heart muscle.
- Severe vomiting, diarrhoea, treatment with high doses of “water tablets” (diuretics) or if you are on a low salt diet.
- Increased levels of potassium in your blood.
- Problems with your adrenal glands (hormone producing glands on top of the kidneys).
- Diabetes.
- Lupus erythematosus (an autoimmune disease).
- Allergies or asthma.
- Skin reactions such as sunburn or rash after being in the sun or using a sunbed.

Contact your doctor if you experience diarrhoea that is severe, persistent and causes substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

As with any medicine, which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.

Konverge Plus may cause a rise in blood fat levels and uric acid levels (the cause of gout – painful swelling of the joints). Your doctor will probably want to do a blood test from time to time to check these.

It may change the levels of certain chemicals in your blood called electrolytes. Your doctor will probably want to do a blood test from time to time to check these.

Signs of electrolyte changes are: thirst, dryness of the mouth, muscle pain or cramps, tired muscles, low blood pressure (hypotension), feeling weak, sluggish, tired, sleepy or restless, nausea, vomiting, less need to pass urine, a rapid heart rate. **Tell your doctor if you notice these symptoms.**

If you are due to have tests for parathyroid function you should stop taking Konverge Plus before these tests are carried out.

You must tell your doctor if you think that you are (or might become) pregnant. Konverge Plus is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section "Pregnancy and breast-feeding").

Children and adolescents (under 18)
Konverge Plus is not recommended for children and adolescents under the age of 18.

Other medicines and Konverge Plus
Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:
* **Other blood pressure lowering medicines,** as the effect of Konverge Plus can be increased. Your doctor may need to change your dose and/or to take other precautions:
  If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Konverge Plus if" and "Warnings and precautions").
* **Lithium** (a medicine used to treat mood swings and some types of depression), used at the same time as Konverge Plus may increase the toxicity of lithium. If you have to take lithium your doctor will measure your lithium blood levels.
* **Diltiazem,** verapamil, used for heart rhythm problems and high blood pressure.
* **Rifampicin, erythromycin, clarithromycin,** used for tuberculosis and other infections.
* **St. John's wort** (Hypericum perforatum), a herbal remedy for treatment of depression.
* **Cisapride,** used to increase food movement in the stomach and gut.
* **Diphemanil,** used to treat a slow heartbeat or reduce sweating.
* **Halofantrine,** used for malaria.
* **Vincamine IV,** used to improve circulation to the nervous system.
* **Amantadine,** used for Parkinson's disease.
* **Potassium supplements, salt substitutes containing potassium, "water tablets"** (diuretics), heparin (for thinning the blood and prevention of blood clots), ACE inhibitors (for blood pressure lowering), laxatives, steroids, adrenocorticotrophic hormone (ACTH), carbenoxolone (a medicine used to treat mouth and stomach ulcers), penicillin G sodium (also called benzylpenicillin sodium, an antibiotic), certain pain killers such as acetylsalicylic acid ("aspirin") or salicylates. Using these medicines at the same time as Konverge Plus may alter the levels of potassium in your blood.
* **Non-Steroidal Anti-Inflammatory Drugs** (NSAIDs, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis), used at the same time as Konverge Plus may increase the risk of kidney failure. The effect of Konverge Plus can be decreased by NSAIDs. In case of high dosages of salicylate the toxic effect on central nervous system may be increased.
* **Sleeping tablets, sedatives and anti-depressant medicines** as using these medicines together with Konverge Plus may cause a sudden drop in blood pressure when standing up.
* **Colesevelam hydrochloride,** a drug that lowers the level of cholesterol in your blood, as the effect of Konverge Plus may be decreased. Your doctor may advise you to take Konverge Plus at least 4 hours before colesevelam hydrochloride.
* **Certain antacids** (indigestion or heartburn remedies) as the effect of Konverge Plus can be slightly decreased.
* **Certain muscle relaxing medicines** such as baclofen and tubocurarine.
* **Anticholinergic agents** such as atropine and biperiden.
* **Calcium supplements.**

* **Dantrolene** (infusion for severe body temperature abnormalities).
* **Simvastatin,** used to lower levels of cholesterol and fats (triglycerides) in the blood.

Also, tell your doctor or pharmacist if you are taking or might take any of the following medicines to:
* **Treat certain mental health problems** such as thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, amisulpride, pimozide, sultopride, tiapride, droperidol or haloperidol.
* **Treat low blood sugar** (e. g. diazoxide) or **high blood pressure** (e.g. beta-blockers, methyldopa) as Konverge Plus can affect how these drugs work.
* **Treat heart rhythm problems** such as mizolastine, pentamidine, terfenadine, dofetilide, ibutilide or erythromycin injections.
* **Treat HIV/AIDS** (e. g. ritonavir, indinavir, nelfinavir)
* **Treat fungal infections** (e. g. ketoconazole, itraconazole, amphotericin).
* **Treat heart problems** such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, bepridil or digitalis.
* **Treat cancers** such as amifostine, cyclophosphamide or methotrexate.
* **Increase blood pressure** and **slow heart rate** such as noradrenaline.
* **Treat infections** such as the antibiotics called tetracyclines or sparfloxacin.
* **Treat gout** such as probenecid, sulfinpyrazone and allopurinol.
* **Lower blood fat levels** such as colestyramine and colestipol.
* **Stop rejection of organ transplants** such as ciclosporin.
* **Lower blood sugar** such as metformin or insulin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Konverge Plus with food and drink
Konverge Plus can be taken with or without food.

Grapefruit juice and grapefruit should not be consumed by people who are taking Konverge Plus. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Konverge Plus.

Take care when drinking alcohol while you are taking Konverge Plus as some people feel faint or dizzy. If this happens to you, do not drink any alcohol.

Elderly patients
If you are over 65 years of age your doctor will regularly check your blood pressure at any dose increase, to make sure that your blood pressure does not become too low.

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Konverge Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Konverge Plus. Konverge Plus is not recommended during pregnancy, and must not be taken when more than 3 months pregnant as it may cause serious harm to your baby if used after the third month of pregnancy.
If you become pregnant during therapy with Konverge Plus please inform and see your physician without delay.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Konverge Plus is not recommended for mothers, who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You may feel sleepy, sick or dizzy or get a headache while being treated for your high blood pressure. If this happens do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

3 How to take Konverge Plus

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

* The recommended dose of Konverge Plus is one tablet per day.
* The tablet can be taken with or without food. Swallow the tablet with some fluid (such as a glass of water). The tablet should not be chewed. Do not take the tablet with grapefruit juice.
* If possible, take your daily dose at the same time each day, for example at breakfast time.

If you take more Konverge Plus than you should
If you take more tablets than you should you may experience low blood pressure with symptoms such as dizziness, fast or slow heart beat.
If you take more tablets than you should or if a child accidentally swallows some go to your doctor or nearest emergency department immediately and take your medicine pack or this leaflet with you.

If you forget to take Konverge Plus
If you forget to take a dose take your normal dose the following day as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Konverge Plus
It is important to continue to take Konverge Plus unless your doctor tells you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If side effects do occur they are often mild and do not require treatment to be stopped.

Although not many people may get them, the following two side effects can be serious:
Allergic reactions with swelling of the face, mouth and/or larynx (voice box) together with itching and rash may occur during treatment with Konverge Plus. **If this happens stop taking Konverge Plus and contact your doctor immediately.**

Severe light-headedness or fainting because Konverge Plus can cause the blood pressure to fall too low in susceptible individuals. **If this happens stop taking Konverge Plus, contact your doctor immediately and lay down flat.**

Konverge Plus is a combination of three active substances. The following information firstly gives the other side effects reported so far with the combination Konverge Plus (besides those already mentioned above) and, secondly, those side effects, which are known for each of the separate substances or when two substances are given together.

To give you an idea of how many patients might get side effects, they have been listed as common, uncommon, rare and very rare.

These are the other side effects known about so far with Konverge Plus:

If these side effects occur they are often mild and you do not need to stop your treatment.

Common
(affects less than 1 in 10 people)
Upper respiratory tract infection; sore throat and nose; urinary tract infection; dizziness; headache; awareness of heartbeat; low blood pressure; nausea; diarrhoea; constipation; muscle spasm; joint swelling; feeling more of an urge to pass urine; weakness; swelling of ankles, feet, legs, hands or arms; tiredness; abnormal laboratory values.

Uncommon
(affects less than 1 in 100 people)
Dizziness on standing up; vertigo; fast heartbeat; feeling faint; redness and warm feeling of the face; cough; dry mouth; muscular weakness; inability to get or maintain an erection.

These are the side effects, which are known for each of the separate substances or when two substances are given together:

They may be side effects for Konverge Plus, even if they have not been seen so far with Konverge Plus.

Common
(affects less than 1 in 10 people)
Bronchitis; stomach and gut infection; vomiting; increased blood sugar; sugar in urine; confusion; feeling sleepy; runny or stuffy nose; sore throat; abdominal pain; heartburn; stomach discomfort; flatulence; pain in the joints or bones; back pain; skeletal pain; blood in the urine; flu-like symptoms; chest pain; pain.

Uncommon
(affects less than 1 in 100 people)
Reduced number of a type of blood cells known as platelets, which can result in bruising easily or a prolonged bleeding time; anaphylactic reactions; abnormally reduced appetite (anorexia); problems sleeping; irritability; mood changes including feeling anxious; feeling "down" or depressed; shiver; sleep disturbances; distorted sense of taste; loss of consciousness; reduced sense of touch; tingling sensations; visual disturbance (including double vision and blurred vision); worsening of shortsightedness; ringing in the ears (tinnitus); angina (pain or uncomfortable feeling in the chest, known as angina pectoris); difficulty breathing; rash; loss of hair; allergic inflammation of the skin; redness of skin; purplish spots or patches on the skin due to small haemorrhages (purpura); discolouration of the skin; red itchy bumps (hives); increased sweating; itching; eruption of the skin; skin reactions to light such as sunburn or rash; muscle pain; problems to pass urine; feeling urge to pass urine at night; breast enlargement in men; decreased sexual desire; swelling of the face; feeling unwell; weight increase or decrease; exhaustion.

Rare
(affects less than 1 in 1,000 people)
Swollen and sore salivary glands; reduced number of white cells in the blood, which could increase the risk of infections; low red blood cell count (anaemia); bone marrow damage; restlessness; feeling uninterested (apathy); fits (convulsions); objects you look at appearing yellow; dry eyes; irregular heart beat; blood clots (thrombosis, embolism); fluid accumulation in the lungs; pneumonia; inflammation of blood vessels and small blood vessels in the skin; inflammation of the pancreas; yellowing of the skin and eyes; acute inflammation of the gall bladder; symptoms of lupus erythematosus such as rash, joint pains and cold hands and fingers; peeling and blistering of the skin; impaired movement; acute kidney failure; non-infectious kidney inflammation; poor kidney function; fever.

Very Rare
(affects less than 1 in 10,000 people)
High muscle tension; numbness of hands or feet; heart attack; inflammation of the stomach; thickening of the gums; blockage in the gut; inflammation of the liver; allergic skin rash.