B. PACKAGE LEAFLET

Karvezide 150/12.5 mg tablets

Irbesartan/hydrochlorothiazide

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR TABLETS

Your doctor has prescribed this medicine for you. Do not give it to anyone else. This leaflet contains a summary of the information on your medicine. If you have questions or want more information, please ask your doctor or pharmacist. Keep this leaflet while you are taking Karvezide tablets, as you may want to read it again.

COMPOSITION

The active substances in Karvezide tablets are irbesartan and hydrochlorothiazide. Each tablet of Karvezide 150/12.5 mg contains 150 mg irbesartan and 12.5 mg hydrochlorothiazide.

The tablets contain the following excipients: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, colloidal hydrated silica, pregelatinised maize starch, red and yellow ferric oxides (E172).

Karvezide tablets are supplied in blister packs of 28, 56 or 98.

TYPE OF MEDICINE

Karvezide is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body that binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.

Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in Karvezide work together to lower blood pressure further than if either was given alone.

MARKETING AUTHORISATION HOLDER

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WHEN SHOULD Karvezide BE USED?

Karvezide is used in the treatment of high blood pressure (hypertension), when a combination of two active substances is deemed appropriate. This is usually the case when treatment with one active substance alone did not provide adequate control of your blood pressure.

Your doctor measured your blood pressure and found it to be above the normal range for your age. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. In some instances, this may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus, measurement of the blood pressure is necessary to verify if it is in the normal range or not.

High blood pressure can be treated and controlled with medicines such as Karvezide. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). Your doctor may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking and swimming.

IMPORTANT INFORMATION BEFORE TAKING Karvezide:

When should Karvezide not be used?

Do not take Karvezide if:

- you are or think you may be pregnant,
- you are planning to become pregnant,
- you are breast-feeding,
- you have severe liver or kidney problems (ask your doctor if you have any doubt),
- you have difficulty in producing urine,
- you have a condition which is associated with persistently high calcium or low potassium levels in your blood, or
- you are allergic to any of the ingredients (see “Composition”) or to sulfonamide-derived medicines.

If any of the above apply to you, inform your doctor or pharmacist first and ask for their advice.

Other appropriate precautions before use

There are certain conditions that you may have, or have had, which require special care before or while taking Karvezide. Therefore, before taking this medicine, you should have told your doctor if you suffer from:

- excessive vomiting or diarrhoea,
- kidney problems, including kidney transplantation,
- heart problems,
- liver problems,
- diabetes or
- lupus erythematosus (also known as lupus or SLE).

You should also tell your doctor if you are on a low-salt diet.

Signs such as abnormal thirst, dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea, vomiting, or an abnormally fast heart beat may indicate an excessive effect of hydrochlorothiazide (contained in Karvezide) for which you should consult your doctor.

If you are to undergo any surgery or receive anaesthetics, you should make sure the doctor knows that you are taking Karvezide tablets.

Hydrochlorothiazide contained in this medication could produce a positive result in an anti-doping test.

CAN YOU TAKE Karvezide WITH OTHER MEDICINES?

You should have informed your doctor of any medicines you are taking. These include medicines obtained without prescription.

Diuretic agents such as the hydrochlorothiazide contained in Karvezide may interact with other medicines. Preparations containing lithium should not be taken with Karvezide without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium sparing medicines, other diuretics (water tablets), some laxatives, medicines for the treatment of gout, therapeutic vitamin D supplements, medicines to control heart rhythm or for diabetes (oral agents or insulins). It is also important for your doctor to know if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killers or arthritis medicines.

CAN Karvezide BE USED DURING PREGNANCY OR BREAST-FEEDING?

Karvezide should not be used during pregnancy or if you are breast-feeding (see "When should Karvezide not be used").

CAN YOU DRIVE OR OPERATE MACHINERY WHILE TAKING Karvezide?

Karvezide is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, you should consult your doctor before attempting such activities.

HOW SHOULD YOU TAKE Karvezide?

The tablets should be taken regularly as directed by your doctor.

Karvezide will usually be prescribed by your doctor when your previous treatment for high blood pressure did not provide appropriate blood pressure reduction. Your doctor will instruct you how to switch from the previous treatment to Karvezide.

The usual dose of Karvezide is one tablet a day. The maximal blood pressure lowering effect should be reached 6-8 weeks after beginning treatment. Should your blood pressure not be appropriately reduced with Karvezide, your doctor may prescribe an additional medicine.

Karvezide can be taken with or without food. The tablets should be swallowed with a drink of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Karvezide until your doctor tells you otherwise.

Karvezide should not be given to children (< 18 years).

OVERDOSE

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately.

MISSING A DOSE

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for the missed dose.

ARE THERE SIDE EFFECTS WHEN TAKING Karvezide?

All medicines may cause some side effects.

Side effects with Karvezide are generally rare and of a temporary nature. They are generally mild and do not normally require treatment to be interrupted.

In clinical studies, symptoms or feelings most often reported by patients taking Karvezide or placebo (sugar tablets) included: headache, dizziness, fatigue, nausea/vomiting or abnormal urination. Of these, only fatigue was reported more often by patients taking Karvezide compared to patients taking placebo.

As for any combination of two active substances, side effects associated with each individual component cannot be excluded. In clinical studies with irbesartan alone, only minor injuries, most likely related to physical activity (like muscle and joint sprains), and on rare occasions flushing, were reported more often by patients taking irbesartan compared to patients taking placebo (sugar tablets). It was not clear if these were due to the medicine. The symptoms or feelings most often reported by patients taking irbesartan or placebo included: respiratory infections (like colds and flu), aches and pains (like headache and muscle aches), and dizziness. None of these was reported more often by patients taking irbesartan compared to patients taking placebo.

Rarely, patients taking similar medicines have developed localised swelling of the face, lips and/or tongue. This might also occur occasionally with irbesartan. If you think you are developing such a reaction or get short of breath stop taking Karvezide and seek immediate medical attention.

The other component of Karvezide (hydrochlorothiazide) has been associated rarely with other more serious side effects mainly affecting the blood, the skin or the kidneys. While this was not observed with Karvezide, occurrence of such side effects cannot be excluded.

If you notice abnormal symptoms or feelings while taking Karvezide, you should inform your doctor or pharmacist and ask for their advice.

HOW SHOULD YOU STORE YOUR Karvezide TABLETS?

Keep all medicines out of the reach of children.

Do not store above 30°C.

Store in the original package.

You will see an expiry date on the carton and on the blister. Do not use the tablets after this date. Do not remove the tablets from the blister pack until you are ready to take the medicine.

DATE OF LAST REVISION OF THIS LEAFLET

OTHER INFORMATION

If you would like more information on your disease or treatment, you should ask your doctor or pharmacist.

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Karvezide 300/12.5 mg tablets

Irbesartan/hydrochlorothiazide

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR TABLETS

Your doctor has prescribed this medicine for you. Do not give it to anyone else. This leaflet contains a summary of the information on your medicine. If you have questions or want more information, please ask your doctor or pharmacist. Keep this leaflet while you are taking Karvezide tablets, as you may want to read it again.

COMPOSITION

The active substances in Karvezide tablets are irbesartan and hydrochlorothiazide. Each tablet of Karvezide 300/12.5 mg contains 300 mg irbesartan and 12.5 mg hydrochlorothiazide.

The tablets contain the following excipients: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, colloidal hydrated silica, pregelatinised maize starch, red and yellow ferric oxides (E172).

Karvezide tablets are supplied in blister packs of 28, 56 or 98.

TYPE OF MEDICINE

Karvezide is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body that binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.

Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in Karvezide work together to lower blood pressure further than if either was given alone.

MARKETING AUTHORISATION HOLDER

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WHEN SHOULD Karvezide BE USED?

Karvezide is used in the treatment of high blood pressure (hypertension), when a combination of two active substances is deemed appropriate. This is usually the case when treatment with one active substance alone did not provide adequate control of your blood pressure.

Your doctor measured your blood pressure and found it to be above the normal range for your age. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. In some instances, this may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus, measurement of the blood pressure is necessary to verify if it is in the normal range or not.

High blood pressure can be treated and controlled with medicines such as Karvezide. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). Your doctor may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking and swimming.

IMPORTANT INFORMATION BEFORE TAKING Karvezide:

When should Karvezide not be used?

Do not take Karvezide if:

- you are or think you may be pregnant,
- you are planning to become pregnant,
- you are breast-feeding,
- you have severe liver or kidney problems (ask your doctor if you have any doubt),
- you have difficulty in producing urine,
- you have a condition which is associated with persistently high calcium or low potassium levels in your blood, or
- you are allergic to any of the ingredients (see “Composition”) or to sulfonamide-derived medicines.

If any of the above apply to you, inform your doctor or pharmacist first and ask for their advice.

Other appropriate precautions before use

There are certain conditions that you may have, or have had, which require special care before or while taking Karvezide. Therefore, before taking this medicine, you should have told your doctor if you suffer from:

- excessive vomiting or diarrhoea,
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Hydrochlorothiazide contained in this medication could produce a positive result in an anti-doping test.

CAN YOU TAKE Karvezide WITH OTHER MEDICINES?

You should have informed your doctor of any medicines you are taking. These include medicines obtained without prescription.

Diuretic agents such as the hydrochlorothiazide contained in Karvezide may interact with other medicines. Preparations containing lithium should not be taken with Karvezide without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium sparing medicines, other diuretics (water tablets), some laxatives, medicines for the treatment of gout, therapeutic vitamin D supplements, medicines to control heart rhythm or for diabetes (oral agents or insulins). It is also important for your doctor to know if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killers or arthritis medicines.

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HOW SHOULD YOU TAKE Karvezide?

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Karvezide can be taken with or without food. The tablets should be swallowed with a drink of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Karvezide until your doctor tells you otherwise.

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OVERDOSE

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately.

MISSING A DOSE

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ARE THERE SIDE EFFECTS WHEN TAKING Karvezide?

All medicines may cause some side effects.

Side effects with Karvezide are generally rare and of a temporary nature. They are generally mild and do not normally require treatment to be interrupted.

In clinical studies, symptoms or feelings most often reported by patients taking Karvezide or placebo (sugar tablets) included: headache, dizziness, fatigue, nausea/vomiting or abnormal urination. Of these, only fatigue was reported more often by patients taking Karvezide compared to patients taking placebo.

As for any combination of two active substances, side effects associated with each individual component cannot be excluded. In clinical studies with irbesartan alone, only minor injuries, most likely related to physical activity (like muscle and joint sprains), and on rare occasions flushing, were reported more often by patients taking irbesartan compared to patients taking placebo (sugar tablets). It was not clear if these were due to the medicine. The symptoms or feelings most often reported by patients taking irbesartan or placebo included: respiratory infections (like colds and flu), aches and pains (like headache and muscle aches), and dizziness. None of these was reported more often by patients taking irbesartan compared to patients taking placebo.

Rarely, patients taking similar medicines have developed localised swelling of the face, lips and/or tongue. This might also occur occasionally with irbesartan. If you think you are developing such a reaction or get short of breath stop taking Karvezide and seek immediate medical attention.

The other component of Karvezide (hydrochlorothiazide) has been associated rarely with other more serious side effects mainly affecting the blood, the skin or the kidneys. While this was not observed with Karvezide, occurrence of such side effects cannot be excluded.

If you notice abnormal symptoms or feelings while taking Karvezide, you should inform your doctor or pharmacist and ask for their advice.

HOW SHOULD YOU STORE YOUR Karvezide TABLETS?

Keep all medicines out of the reach of children.

Do not store above 30°C.

Store in the original package.

You will see an expiry date on the carton and on the blister. Do not use the tablets after this date. Do not remove the tablets from the blister pack until you are ready to take the medicine.

DATE OF LAST REVISION OF THIS LEAFLET

OTHER INFORMATION

If you would like more information on your disease or treatment, you should ask your doctor or pharmacist.

Further information
For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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