

PATIENT INFORMATION LEAFLET

INSUFOR 500 mg Film Coated Tablets

For oral use.

- **Active Substance:** Each film coated tablets contains 500 mg metformin hydrochloride.
- **Excipients:** Kollidon CL, pregelatinized maize starch, povidone K-30, povidone K-90, magnesium stearate, polyvinyl alcohol, talc, polyethylene glycol, titanium dioxide.

Read all of this leaflet carefully before you start taking this medicine, because it includes special 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. Do not pass it on to others.*
- *If you go to doctor or hospital at the time of using this medicine, please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.*

In this leaflet:

- 1. What is INSUFOR and what it is used for?**
- 2. Before you use INSUFOR**
- 3. How to use INSUFOR?**
- 4. Possible side effects**
- 5. How to store INSUFOR?**

Headings are included.

1. WHAT IS INSUFOR AND WHAT IT IS USED FOR?

- Each film coated tablet is presented to use in blister packaging of 90 tablets that contains 500 mg metformin hydrochloride.
- INSUFOR is white coloured, round, biconvex film coated tablet.
- INSUFOR is included the drug group which named as oral antidiabetic (biguanides). These types of drugs are used for treatment of diabetes.
- Insulin is a hormone produced by the pancreas that makes your body takes glucose (sugar) from the blood. Your body uses glucose to produce energy or stores it for future use.

If you have diabetes, it means your pancreas does not make enough insulin or your body is not able to use properly the insulin it produces. This leads to a high level of glucose in your blood. INSUFOR helps to lower your blood glucose to as normal a level as possible.

- INSUFOR is used to treat patients with type 2 diabetes (a type of diabetes, also called ‘non-insulin dependent diabetes’) when diet and exercise alone have not been enough to control your blood glucose levels. It is used particularly in overweight patients.
- Adults can take INSUFOR on its own or together with other medicines to treat diabetes (medicines taken by mouth or insulin).
- Children 10 years and over and adolescents can take INSUFOR on its own or together with insulin.

2. BEFORE YOU USE INSUFOR

DO NOT USE INSUFOR in the following conditions

If:

- You are allergic to metformin or any of the other excipients in the content of metformin or INSUFOR (see excipients list)
- You have kidney or liver problems
- You have renal or liver impairment and when kidney function disorders (serum creatine level is > 1.5 mg/dl in men and > 1.4 mg/dl in women, or in abnormal creatine clearance)
- You have uncontrolled diabetes accompanied with severe hyperglycemia (high blood glucose), nausea, vomiting, dehydration, rapid weight loss or ketoacidosis.

Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or unusual fruity odor of the breath.

- There is accumulation of acid ions that must be excreted by kidney or over loss of bicarbonate ions (metabolic acidosis)

Metabolic acidosis symptoms are characterized case with disorder of consciousness, foziness, sleep disorder, vomiting, nausea, headache. When these symptoms are seen in you, please contact with your doctor.

- You lost too much water from your body (dehydration), such as due to long-lasting or severe diarrhea, or if you have vomited several times in a row.

Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (Please see Section ‘**USE INSUFOR WITH CAUTION in the following conditions**’ below).

- You have a severe infection risk affecting your lung or bronchial system or your kidney.

Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (Please see Section ‘**USE INSUFOR WITH CAUTION in the following conditions**’ below).

- You are treated for heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties, have a systemic disease (sepsis) which consists of microorganism or pathogen risks in blood or tissue.

This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (Please see Section ‘**USE INSUFOR WITH CAUTION in the following conditions**’ below).

- You drink a lot of alcohol,
- You are breast-feeding.

You tell your doctor that you are using INSUFOR in the following conditions:

If;

- You will get any operation about X-ray or scan that need to be given iodine contrast media that are a type of medicine into your bloodstream,
- You will undergo major surgery, you must stop using INSUFOR for a certain period of time before and after the examination or the surgery.

Your doctor will decide whether you need any other treatment for this time.

It is important that you follow your doctor’s instructions precisely.

USE INSUFOR WITH CAUTION in the following conditions

If:

Please take care the lactic acidosis as a particular risk.

INSUFOR may cause a very rare, but serious complication called lactic acidosis, particularly if your kidneys are not working properly. The risk of lactic acidosis is also increased with uncontrolled diabetes, prolonged fasting or alcohol intake.

Symptoms of lactic acidosis are vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing.

If this disorder happens to you, you may need immediate hospital treatment, because lactic acidosis may lead to coma. Discontinue using INSUFOR immediately and contact a doctor or the nearest hospital straight away.

INSUFOR on its own does not cause hypoglycemia (a blood glucose level which is too low). However, if you use INSUFOR together with other medicines to treat diabetes that can cause hypoglycemia (such as sulfonylureas, insulin, meglitinides), there is a risk of hypoglycemia. If you experience symptoms of hypoglycemia such as weakness, dizziness, increased sweating, fast heart beating, vision disorders or difficulty in concentration, it usually helps to eat or drink something containing sugar.

Please consult your doctor even if these warnings are valid for you at any time in the past.

Using INSUFOR with food and drink:

INSUFOR can take with foods or after meal.

Do not drink alcohol when you take INSUFOR. Alcohol may increase the risk of lactic acidosis especially if you have liver problems or you have malnutrition. This also applies to medicines that contain alcohol.

Pregnancy

Consult your doctor or pharmacist before use medicine.

During pregnancy, you need insulin to treat your diabetes. Tell your doctor before you use INSUFOR if you are pregnant, you think you might be or are planning to become pregnant; in this case, your doctor may change your treatment.

If you realize to be pregnant during treatment, immediately consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before use medicine.

You do not use INSUFOR if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

INSUFOR on its own does not cause hypoglycemia (a blood glucose level which is too low). This means that INSUFOR will not affect your ability to drive or use machines.

However, take special care if you take INSUFOR together with other medicines to treat diabetes that can cause hypoglycemia (such as sulfonylureas, insulin, meglitinides). Symptoms of hypoglycemia include weakness, dizziness, increased sweating, fast heartbeat, vision disorders or difficulty in concentration. Do not drive or use machines if you start to feel these symptoms.

Important information about some excipients in the content of INSUFOR

If you do not have hypersensitivity to excipients that are content of INSUFOR, a negative effect associated with these substances is not expected.

Using with other medicines

If you will get any operation about X-ray or scan that need to be given iodine contrast medicines that are a type of drug into your bloodstream, **you must discontinue using INSUFOR for a certain period of time before and after the operation.**

If you use INSUFOR together with the following medicines, it may be required to make blood sugar tests more frequent or adjusted INSUFOR dosage by your doctor:

- Diuretics
- Beta-2-agonists used in asthma treatment (like salbutamol or terbutaline)
- Corticosteroids used in severe skin inflammation or asthma treatments
- The other drugs used in diabetes treatment
- Enzyme inhibitors of angiotensin converter (drugs used in treatments of cardiovascular diseases such as high blood pressure or heart failure)

Please inform your doctor or pharmacist if you are taking or took recently any of these drugs with or without prescription.

3. HOW TO USE INSUFOR?

INSUFOR cannot replace the benefits of a healthy lifestyle. Continue to follow diet that recommended by your doctor and get regular exercise when using your medicine.

Instructions for proper use and dose/frequency of administration:

- Unless your doctor has a different recommendation, standard start dose is 500 mg or 850 mg INSUFOR at 2 or 3 times of day in adults. The maximum daily dose is 3000 mg taken as 3 divided doses.
- If you also use insulin, your doctor will tell you how to start INSUFOR.

Monitoring:

Your doctor will follow regularly blood glucose levels and will determine dose of INSUFOR according to your blood glucose levels.

Your doctor will want to check at least once a year how well your kidneys work. You may need more frequent checks if your kidneys are not working normally.

Administration route and method:

Take INSUFOR with or after a meal. This will avoid occurring side effects affecting your digestive system of this medicine.

Do not crush or chew the tablets.

Swallow INSUFOR tablet with sufficiently water.

- If you take one dose a day, take it in the morning (breakfast)
- If you take two divided doses a day, take them in the morning (breakfast) and evening (dinner)
- If you take three divided doses a day, take them in the morning (breakfast), at noon (lunch) and in the evening (dinner)

Different age groups:

Usage in children:

Standard start dose of INSUFOR is 500 mg or 850 mg once a day in children 10 years and older and adolescent. The maximum dose is 2000 mg taken as 2 or 3 divided doses. Treatment of children between 10 and 12 years of age, because of insufficient experience in this age group is only recommended on specific advice of your doctor.

- Monitoring:

Your doctor will perform INSUFOR dose that need to be taken in children and adolescents according to your blood sugar level. Talk to your doctor regularly.

Usage in elderly:

Your kidney function may deteriorate with aging. Your doctor will perform INSUFOR dose that should be taken according to your kidney function. Talk to your doctor regularly.

- Monitoring:

Your doctor will perform INSUFOR dose that should be taken according to your blood sugar level. Talk to your doctor regularly.

Your doctor will want to check at least once a year how well your kidneys work.

Special usage cases:

Renal failure:

INSUFOR should not be used in patients with renal failure.

When kidney function disorder ($K_{kr} < 60$ ml/min.), serum creatine level (in men >1.5 mg/dl and in women >1.4 mg/dl) is contraindicated.

In elderly people, metformin hydrochloride dose should be adjusted according to kidney functions due to decreasing potential of kidney functions. Regular control of renal functions is necessary.

Liver failure:

INSUFOR should not be used in patients with liver failure.

Talk with your doctor or pharmacist if you have impression that it is too strong or too weak effect of INSUFOR.

If you use more INSUFOR than you should:

If you have used more INSUFOR than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. If this symptoms of mentioned lactic acidosis happen to you, you may need immediate medical attention. So, you should contact your doctor.

If you use more INSUFOR than you should, talk with a doctor or pharmacist.

If you forget to use INSUFOR:

Do not take a double dose to balance forgotten doses.

If you forget to take medicine, take the next dose at the usual time by making up for a forgotten dose.

Effects that may occur when treatment with INSUFOR is finished:

Unless your doctor has told you to stop treatment, do not discontinue to use INSUFOR.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Side effects can be occurred in people who are sensitive to substances in the content of INSUFOR.

If any of the following occurs, stop using INSUFOR and inform your doctor IMMEDIATELY or consult to emergency department of the nearest hospital to you:

- Lactic acidosis.

Lactic acidosis is a very rare but serious complication particularly if especially your kidneys are not working properly. If this happens to you, you may need immediate treatment. Symptoms of lactic acidosis are vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing.

- Metabolic acidosis that is characterized with consciousness disorder, foziness, sleep disorder, vomiting, nausea and headache.

All of these are very severe side effects. If one of these exists to you, you may need emergency medical attention or hospitalization. All of these very side effects are seen rarely.

If you notice any of the followings, immediately inform your doctor or consult emergency department of the nearest hospital.

- Low vitamin B12 levels in the blood
- Abnormalities in liver function test
- Hepatitis (inflammation of the liver; this may cause tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes).
- Cholestatic hepatitis; characterized situation with jaundice, light-colored stools, itching, asthenia, trichiniasis
- Increasing of liver enzyme level
- Anaemia (hemolytic anaemia)
- Being blood sugar lower than normal that are manifested shivering, diaphoresis, formication in lip and tongue, faintness, tachycardia and restiveness (hypoglycemia)
- Rash on the skin (erythema), skin reactions such as itching, hives
- Skin disorders that are clear with skin eruption that consist of bright, purple colored papules
- Weight loss and cachexia (cachexia), loss of appetite (anorexia)

All of these are severe side effects. They may need emergency medical intervention. Severe side effects are seen rarely.

If you notice any of the followings, inform your doctor:

- Disorders in taste
- Digestion problems such as feeling sick, nausea, vomiting, diarrhea, abdominal pain, intumescence, dyspepsia and loss of appetite. These side effects are generally at the beginning of the treatment. If you spread dosages during a day and take tablets with meal or after meal, these complaints will decrease.
- Prostration (asthenia), dizziness, drowsiness, headache

These are mild side effects of INSUFOR.

Different age groups:

Children and adolescents:

Limited data obtained from children and adolescents showed that side effects were similar in content and severity to those reported in adults.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE INSUFOR

Keep INSUFOR out of the reach and sight of children and its packaging.

Store at room temperature below 30°C.

Use in accordance with expiry date.

Do not use INSUFOR after the expiry date on package.

If you notice failure in product and/or package, do not use INSUFOR.

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