

PATIENT INFORMATION LEAFLET

PANFOR PR (Metformin Hydrochloride 500mg, 750mg, 1000 mg Prolonged Released tablets)

Read all of this leaflet carefully before you start taking using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- a) What Panfor PR is and what it is used for
- b) Before you take use Panfor PR?
- c) How to take use Panfor PR?
- d) Possible side effects
- e) How to store Panfor PR?
- f) Further information

a) WHAT PANFOR PR IS AND WHAT IT IS USED FOR ?

Panfor PR prolonged release tablets contain the active ingredient metformin hydrochloride and belong to a group of medicines called biguanides, used in the treatment of Type 2 (non-insulin dependent) diabetes mellitus.

Panfor PR is used together with diet and exercise to lower the risk of developing Type 2 diabetes in overweight adults, when diet and exercise alone for 3 to 6 months have not been enough to control blood glucose (sugar). You are at high risk of developing Type 2 diabetes if you have additional conditions like high blood pressure, age above 40 years, an abnormal amount of lipids (fat) in the blood or a history of diabetes during pregnancy.

The medicine is particularly effective if you are aged below 45 years, are very overweight, have high blood glucose levels after a meal or developed diabetes during pregnancy.

Panfor PR is used for the treatment of Type 2 diabetes when diet and exercise changes alone have not

been enough to control blood glucose (sugar). Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or their body does not respond properly to the insulin it does make. This causes a build-up of glucose in the blood which can cause a number of serious long-term problems so it is important that you continue to take your medicine, even though you may not have any obvious symptoms.

Panfor PR makes the body more sensitive to insulin and helps return to normal the way your body uses glucose.

Panfor PR is associated with either a stable body weight or modest weight loss.

Panfor PR Prolonged Release Tablets are specially made to release the drug slowly in your body and therefore are different to many other types of tablet containing metformin.

b) BEFORE YOU TAKE USE PANFOR PR

Do not take use Panfor PR

you are allergic to metformin or to any of the other ingredients of this medicine. An allergic reaction may cause a rash, itching or shortness of breath.

- you have liver problems
- you have severely reduced kidney function
- you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual, fruity smell.
- you have lost too much water from your body (dehydration).

Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis.

- you have a severe infection, such as an infection 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.
- you have been treated for acute heart problems or have recently had a heart attack or have severe circulatory problems or breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis.
- you are a heavy drinker of alcohol.
- you are under 18 years of age.

Take special care with Panfor PR

Warnings and precautions

Risk of lactic acidosis.

Metformin may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Panfor PR for a short time if you have a condition that may be associated with dehydration

(Significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Panfor PR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

If you need to have major surgery you must stop taking Panfor PR during and for some time after the procedure.

Your doctor will decide when you must stop and when to restart your treatment with Panfor PR.

During treatment with Panfor PR, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

If you are older than 75 years, treatment with Panfor PR should not be started to lower the risk of developing type 2 diabetes.

You may see some remains of the tablets in your stools. Do not worry-this is normal for this type of tablet.

You should continue to follow any dietary advice that your doctor has given you and you should make

sure that you eat carbohydrates regularly throughout the day Do not stop taking this medicine without speaking to your doctor.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Panfor PR before or at the time of injection. Your doctor will decide when you must stop and when to restart your treatment with Panfor PR. Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dosage of Panfor PR. It is especially important to mention the following:

- Medicines which increase urine production (diuretics (water tablets) such as furosemide).
- Medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors, such as ibuprofen and celecoxib)
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- Steroids such as prednisolone, mometasone, beclometasone.
- Sympathomimetic medicines including epinephrine and dopamine used to treat heart attacks and low blood pressure. Epinephrine is also included in some dental anaesthetics.
- Medicines that may change the amount of Panfor PR in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib).

Taking or Using Panfor PR with food and drink

Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, speak to your doctor in case any changes will be needed to your treatment or monitoring of your blood glucose levels.

This medicine is not recommended if you are breast-feeding or if you are planning to breast-feed your baby.

Driving and using machines

Panfor PR taken on its own does not cause 'hypos' (symptoms of low blood sugar or hypoglycaemia, such as faintness, confusion and increased sweating) and therefore should not affect your ability to drive or use machinery.

You should be aware, however, that Panfor PR taken with other antidiabetic medicines can cause hypos, so in this case you should take extra care when driving or operating machinery.

Important information about some of the ingredients of (Panfor PR)

This medicine contains less than 1 mmol sodium per dosage unit, that is to say it is essentially 'sodium free'.

c) HOW TO TAKE USE Panfor PR ?

Your doctor may prescribe Panfor PR for you to take on its own, or in combination with other oral antidiabetic medicines or insulin.

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

Swallow the tablets whole with a glass of water, do not chew.

Recommended dose

Usually you will start treatment with 500 milligrams Panfor PR daily. After you have been taking Panfor PR for about 2 weeks, your doctor may measure your blood sugar and adjust the dose. The maximum daily dose is 2000 milligrams of Panfor PR.

If you have reduced kidney function, your doctor may prescribe a lower dose.

Normally, you should take the tablets once a day, with your evening meal.

In some cases, your doctor may recommend that you take the tablets twice a day. Always take the tablets with food.

If you take more Panfor PR than you should

If you take extra tablets by mistake you need not worry, but if you have unusual symptoms, contact your doctor. If the overdose is large, lactic acidosis is more likely. Symptoms of lactic acidosis are non-specific, such as vomiting, bellyache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing.

Further symptoms are reduced body temperature and heart beat. If you experience some of these symptoms, you should immediately seek medical attention, as lactic acidosis may lead to coma.

Stop taking Panfor PR immediately and contact a doctor or the nearest hospital straightaway.

If you forget to take Panfor PR

Take it as soon as you remember with some food. Do not take a double dose to make up for a forgotten dose

d) POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur:

Panfor PR may cause a very rare (may affect up to 1 user in 10,000) but very serious side effect called lactic acidosis.

If this happens, you must **stop taking the Panfor PR and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Panfor PR may cause abnormal liver function tests and hepatitis (inflammation of the liver) which may result in jaundice (may affect up to 1 user in 10,000). If you develop yellowing of the eyes and/or skin contact your doctor immediately.

Other possible side effects are listed by frequency as follows:

Very common side effects (may affect more than 1 in 10 people):

- Diarrhoea, nausea, vomiting, stomach ache or loss of appetite. If you get these, do not stop taking the tablets as these symptoms will normally go away in about 2 weeks. It helps if you take the tablets with or immediately after a meal.

Common side effects (may affect up to 1 in 10 people):

- Taste disturbance
- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin).

Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.

Very rare side effects (may affect up to 1 in 10,000 people):

- Skin rashes including redness, itching and hives.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

e) **HOW TO STORE PANFOR PR**

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

Do not use this medicine after the expiry date that is printed on the pack 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 to protect the environment.

STORAGE

- Keep out of reach of children
- Protect from light & moisture
- Store below 30°C in a dry place
- Swallow whole, do not chew or crush the tablet

f) **FURTHER INFORMATION**

What Panfor PR contains?

Panfor PR-500

Metformin Hydrochloride 500 mg Prolonged Release Tablets

Each prolonged release tablet contains

500 mg Metformin Hydrochloride

equivalent to 390 mg Metformin

Panfor PR-750

Metformin Hydrochloride 750 mg Prolonged Release Tablets

Each prolonged release tablet contains

750 mg Metformin Hydrochloride

equivalent to 585 mg Metformin

Panfor PR-1000

Metformin Hydrochloride 1000 mg Prolonged Release Tablets

Each prolonged release tablet contains

1000 mg Metformin Hydrochloride

equivalent to 780 mg Metformin

Inactive Ingredients

Panfor PR-500

Hypromellose (K100M), Carboxymethylcellulose Sodium (Sodium CMC), Magnesium Stearate, Purified Water

Panfor PR-750

Carmellose Sodium (Majol 25000S) , Povidone (Kollidon 90F), Methacrylic acid Dispersion (EudragitL30D55). Macrogol (Polyglycol 6000PF), Magnesium Stearate

Panfor PR-1000

Hypromellose K100M (Anycoat-C), Carmellose Sodium (Majol 25000S), Povidone (Kollidon 90F), Purified Water, Magnesium Stearate

What Panfor PR looks like and contents of the pack?

PRESENTATION

Blister of 10 Tablets.

Box containing 10 blister of 10 Tablets each.

Available Form

Panfor PR-500

White to off white capsule shaped, biconvex, beveled edge tablet, with occasionally mottled appearance, debossed with " 001" on one side and plain on other side.

Panfor PR-750

White to off white capsule shaped, biconvex, uncoated tablet plain on both sides.

Panfor PR-1000

White to off white oval, biconvex, beveled edge, uncoated tablet with occasionally mottled appearance, debossed '089' on one side and plain on other side.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Marketing Authorization Holder

Mega Lifesciences Public Company Limited

Address - 384 Moo 4, Pattana 3 Road,

Bangpoo Industrial Estate,

Soi 6, Preaksa, Muang Samutprakarn,

Samutprakarn 10280, Thailand

Manufactured by:

INVENTIA HEALTHCARE LIMITED

F1-F1/1-F75/1, Additional Ambernath M.I.D.C.,

Ambernath (East), Thane 421506, Maharashtra State, India.

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