PACKAGE LEAFLET:
Information for the patient

METFORMINE
Film-coated tablets
500 mg, 850 mg or 1000 mg
(Metformin hydrochloride)

Read this leaflet carefully before you start taking this medicine.
- 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. WHAT METFORMINE IS AND WHAT IT IS USED FOR
Metformine is an oral antidiabetic which is not chemically or pharmacologically related to sulfonylurea derivatives. Metformine improves glucose tolerance in non-insulin-dependent diabetes mellitus by reducing basal and after-meal blood glucose levels. Metformine also reduces hepatic glucose production, intestinal glucose absorption and improves insulin sensitivity (increases peripheral glucose uptake).
Metformine is indicated in non-insulin-dependent diabetes mellitus when treatment by diet modification alone has not been effective and when the patient is overweight. Metformine may be used alone as initial treatment or in combination with a sulfonylurea derivative.
In insulin-dependent diabetes mellitus, Metformine may be used as adjunctive treatment in patients whose symptoms are difficult to manage.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE METFORMINE
Do not take Metformine:
- if you are hypersensitive to metformin hydrochloride, or to any of the excipients of Metformine tablets;
- in case of diabetic coma or ketoacidosis;
- if you have renal dysfunction;
- if you have chronic hepatic disease;
- if you have cardiac insufficiency or myocardial infarction;
- if you have history of lactic acidosis-associated conditions such as shock or pulmonary insufficiency, alcoholism (acute or chronic) and conditions associated with hypoxia.

Metformine should be discontinued prior to parenteral iodinated contrast media administration and should not be re-administered any sooner than 48 hours and should be withheld until renal function is determined to be normal.

Take special care with Metformine
- Metformine may cause a very rare but serious complication called lactic acidosis, especially if kidney dysfunction is present. Lactic acidosis symptoms are as follows: vomiting, abdominal pain with muscle cramps, malaise and respiratory distress. If you experience one of these symptoms, you might need hospitalization, because lactic acidosis may lead to coma. Immediately discontinue Metformine use and contact a doctor or the nearest hospital.
- Metformine is excreted by the kidneys so it is recommended that kidney function is checked in all patients taking this medicine.
- Discontinue Metformine treatment 2-3 day prior to surgical intervention.
- Metformine use is not recommended in conditions associated with dehydration or in patients suffering from infection or trauma.
- In patients who continuously use Metformine, annual check of Vitamin B12 levels is recommended, as evidence exists that this medicine may decrease Vitamin B12 absorption.
- Blood glucose levels should be checked during concomitant use of Metformine with a sulfonylurea derivative or insulin as their combination may cause hypoglycemia.
- Due to risk of hypoglycemia, treatment with Metformine and insulin of a patient with diabetes mellitus should take place in hospital until optimal doses are determined.

Other medicines and Metformine
Use of Metformine with other medicines may influence Metformine or other medicines' effect.
Please, contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including medicines without a prescription.
Do not forget to inform your doctor that you are taking Metformine if any other medicines are prescribed to you.
It is particularly important to tell your doctor that you are taking the following medicines:
- cationic medicines, cimetidine, furosemide, parenteral iodinated contrast media, nifedipine, topiramate, rilpivirine as these medicines may affect metformine plasma concentration;
- furosemide, clomiphene, because Metformine may influence their effect;
- thiazide and loop diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking medicines and isoniazid because they antagonize the blood glucose lowering effect of metformin;
- other antidiabetic medicines, angiotensin converting enzyme (ACE) inhibitors, anabolic steroids, monoamine oxidase (MAO) inhibitors, and alcohol, because they could lead to loss of glycemic control. Careful patient monitoring is required to maintain an optimal glycemic control when these medicines are used concomitantly with Metformin;
- ketotifen, because of depressed thrombocyte count when it is used with Metformine.

Taking Metformine with food and drinks
Metformine may cause hypoglycemia if taken with alcohol.

Pregnancy
Metformine should not be used during pregnancy.

Breast - feeding
Do not take Metformine if you are breast – feeding, because it may be distributed into breast milk.

Driving and using machinery
Car drivers and machinery users should be alerted to the symptoms of hypoglycemia and its effects on vigilance when Metformine is used in combination with a sulfonylurea derivative and/or insulin.

3. HOW TO TAKE METFORMINE
Always take Metformine tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you feel that Metformine effect is too strong or too weak.
There is no fixed dose of Metformine for diabetes mellitus treatment. The dose should be individualized based on its effectiveness and tolerance without exceeding maximum daily dose of 3 g. Treatment is initiated with a small dose, which is gradually increased in order to avoid gastrointestinal side effects and determine the minimal required dose for optimal glycemic control.

Dosage is as follows:
Adults:
the usual initial dosage is 500 mg twice daily or 850 mg twice daily taken in the morning and evening with meals. The dose may be increased by 500 mg every week, given in separate doses up to a maximum of 3000 mg daily. Metformine may be used twice daily up to 1700 – 2000 mg daily (e.g. 1000 mg twice daily, morning and evening with meals). If a dose of 2500 - 2550 mg is required, it might be better tolerated if it is given three times daily with food.

Elderly:
Metformine should be carefully used in elderly patients since aging is associated with reduced renal function which may lead to medicine's accumulation in the body and consequent lactic acidosis. Thus, renal function should be monitored in this patient category in order to determine the exact dose.

Children:
In children 10 years of age or older the usual initial metformin dose is 500 mg twice daily. The dose may be increased by 500 mg daily at weekly intervals until the desired glycemic response is achieved or up to a maximum dosage of 2000 mg daily.

If you take more Metformine than you should
If you take more Metformine tablets than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on the actions that should be taken.

If you forget to take Metformine
If you forget to take one or more doses, take the next dose at the next prescribed time.
Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody manifests them.
The most frequent side effects are:
- gastrointestinal disturbances (anorexia, nausea and vomiting, abdominal disturbance, dyspepsia, diarrhea and metallic taste). These disturbances are usually moderate and may be avoided by taking the medicine with or after meals. Sometimes temporary Metformine dose reduction might be necessary. It is important not to discontinue Metformine treatment at the first symptoms of intolerance, as they may disappear spontaneously;
- lactic acidosis, which might be associated with non-specific symptoms such as myalgia, malaise, respiratory distress, somnolence and psychic disturbance;
- in rare cases, skin reactions have been observed such as redness, rash and urticarial reactions;
- decrease of vitamin B12 absorption.

If any of the side effects gets worse or if you notice side effects not mentioned in this leaflet, please contact your doctor or pharmacist.

5. HOW TO STORE METFORMINE
Keep out of the reach and sight of children.
Do not use the tablets after the expiry date which is stated on the packaging.
Store below 25°C.
Keep in the original packaging to protect it from light.

6. OTHER INFORMATION
What Metformine Film – coated tablets contain
The active substance is metformin hydrochloride.
Each film-coated tablet contains 500 mg, 850 mg or 1000 mg metformin hydrochloride.
Excipients for the 500 mg film-coated tablet are: microcrystalline cellulose, povidone, sodium starch glycolate, magnesium stearate, talc, Opadry II white.
Excipients for the 850 mg film-coated tablet are: povidone, colloidal anhydrous silica, magnesium stearate, Opadry II white.
Excipients for the 1000 mg film-coated tablet are: povidone, colloidal anhydrous silica, sodium starch glycolate, magnesium stearate, Opadry II white.

Contents of the pack
500 mg film-coated tablet: carton box with 30 tablets.
850 mg film-coated tablet: carton box with 30 and 60 tablets.
1000 mg film-coated tablet: carton box with 30 tablets.

Explanatory of the illustration icons on the packaging:

Ask your doctor or pharmacist.

Content. Warning.

Tablet shape **(500 mg).** Tablet shape **(850 mg, 1000 mg).**

Marketing Authorisation Holder (MAH) and Manufacturer:

Profarma sh.a.
Rruga "Myslym Keta"
Tel.: 00 355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in November 2015.

SPECIFICATION CROPING AREA 12x19 cm