



PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986

The medicine is dispensed with
a doctor's prescription only

Glucophage® Caplets

Composition

Each caplet contains:
Metformin Hydrochloride 850 mg

For the list of the inactive ingredients in the
preparation, see section 6 - "Further Information".

**Read this leaflet carefully in its entirety before
using this medicine.** This leaflet contains concise
information about the medicine. If you have further
questions, refer to the doctor or pharmacist.

**This medicine has been prescribed for the
treatment of your ailment. Do not pass it on
to others. It may harm them even if it seems to
you that their ailment is similar.**

This medicine is not intended for children and
adolescents.

Warnings regarding lactic acidosis

Glucophage may cause a very rare severe
complication called lactic acidosis (high mortality
rate when left untreated), especially if your kidneys
do not work properly. The risk for lactic acidosis
increases when your diabetes is not controlled, if
you are fasting for a long time or if you consume
alcohol, dehydration due to severe diarrhea or
vomiting, if you suffer from liver problems or from
any medical condition accompanied by a lack of
oxygen supply to the body organs (such as acute
and severe heart diseases).

It is important to comply with the medicinal
treatment, to follow instructions for a proper diet
and to comply with a regular exercise program
because this may reduce the risk of lactic acidosis.
Development of the disease may be without special
symptoms. Symptoms of lactic acidosis include:
vomiting, abdominal pain with muscle cramps,
a general unwell feeling with severe fatigue and
breathing difficulties. Additional symptoms include
reduced body temperature and heart rate.

**If you experience these symptoms, stop taking
the medicine immediately and refer to a doctor
or emergency room immediately, since lactic
acidosis may cause a coma.**

Warnings regarding hypoglycemia

Glucophage as a monotherapy does not cause
hypoglycemia (low blood glucose levels). However,
if you are taking Glucophage in combination with
other medicines for the treatment of diabetes that
may cause hypoglycemia (e.g., medicines of the
sulphonylurea group, insulin, meglitinides), there is a
risk of developing hypoglycemia. If you experience
symptoms of hypoglycemia, such as: weakness,
tremor, dizziness, headache, increased sweating,
hunger, fast heart rate, vision disturbances, or
difficulty concentrating, it is recommended to eat
or drink something that contains sugar.

If you experience the effects mentioned above, do
not drive or use machinery.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of
diabetes as a monotherapy or in combination with
other medicines to treat diabetes.

Therapeutic group:

The active ingredient belongs to the biguanide
group.



circulation problems (such as shock)
or have breathing difficulties - this may
lead to reduced oxygen supply to body
tissues and to a risk of developing lactic