

Each film-coated tablet contains 500 mg Metformin Hydrochloride equivalent to 390 mg Metformin base.

Indication

As an adjunct to adequate diet and exercise, **Forbetic®** is an oral anti-diabetic agent (biguanide) intended for the treatment of type II diabetes. In adults, **Forbetic®** may be given alone or with other oral antidiabetic agents, or with insulin. In children from 10 years old and adolescents, **Forbetic®** may be given alone or with insulin.

A reduction of diabetic complications has been shown in overweight type II diabetic adult patients treated with Metformin as first-line therapy after diet therapy.

Dosage

The initial dosage is usually one tablet of Metformin hydrochloride 500 mg once daily in children from 10 years old and adolescents and one tablet of Metformin hydrochloride 500 mg 2 or 3 times daily in adults. The maximum recommended dose is 2 g daily in children and 3 g daily in adults (taken as 2 or 3 divided doses). In cases of decreased renal function, the dosage should be adjusted based on renal function.

Contra-indications

- Known hypersensitivity to Metformin hydrochloride or any of the product ingredients
- Severe destabilization of diabetes (Ketoacidosis or pre-coma)
- Renal insufficiency, even if moderate (impairment of kidney function with increased blood creatinine levels or decreased creatinine clearance < 60 ml/mm)
- Infectious diseases (for example respiratory tract infection, urinary tract infection)
- Following an X-ray examination involving the use of iodinated contrast media (for example intravenous urography, angiography)
- Diseases which may cause tissue hypoxia (heart failure, recent myocardial infarction, respiratory insufficiency, shock)
- Hepatic insufficiency (impaired liver function)
- Persistent or severe diarrhoea, recurrent vomiting
- Excessive consumption of alcoholic beverages
- During breast-feeding.

Precautions

Vomiting, abdominal pain with muscle cramps and / or a general feeling of malaise with severe fatigue occurring during therapy may be signs of serious destabilization of your diabetes (diabetic Ketoacidosis or lactic acidosis) requiring specific treatment.

If this occurs, you should stop taking **Forbetic®** immediately and consult your doctor promptly. Lactic acidosis is a medical emergency and must be treated in a hospital. The most effective way to remove lactate and Metformin from the blood is haemodialysis.

Certain illnesses or medications such as corticosteroids, diuretics, Beta2-agonists (e.g. salbutamol, terbutaline) and angiotensin-converting enzyme inhibitors may cause more or less severe destabilization of diabetes.

Pregnancy / Breast-Feeding

During pregnancy, treatment of diabetes is based on insulin therapy. If you discover that you are pregnant while taking **Forbetic®** your treatment will be replaced by insulin. Inform your doctor so that he/she may make the necessary changes to your treatment. Inform your doctor if you wish to become pregnant.

Interactions

Corticosteroids, nonsteroidal anti-inflammatory agents, antihypertensive agents of the angiotensin-converting enzyme inhibitors class, diuretics, Beta2-agonists (e.g. salbutamol, terbutaline), iodinate contrast media or medications containing alcohol, even if an over-the-counter medication is involved.

Side effects

They are presented by frequencies which are defined as follows: very common: $\geq 10\%$; common: $< 10\%$, very rare: $\geq 1\%$ and isolated cases: $< 0.01\%$

Very common: Gastrointestinal discomfort such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite may occur especially at the beginning of treatment.

These symptoms are generally transient and can be reduced by taking the tablets with meals. Should symptoms persist, stop the treatment and consult your doctor.

Common: Taste disturbance.

Very rare: Lactic acidosis is very serious complication, which results in vomiting, abdominal pain with muscle cramps and/or a general feeling of malaise with severe fatigue and which requires specific treatment. If this occurs you should stop taking **Forbetic®** immediately and consult your doctor promptly. Lactic acidosis is a medical emergency and must be treated in a hospital.

Skin reactions such as erythema (red skin), itching or urticaria (eruption with itching). Decreased vitamin B₁₂ levels

Isolated cases: Liver function tests abnormalities or hepatitis resolving upon **Forbetic®** discontinuation.

Storage: Store below 30°C.

KEEP OUT OF THE REACH OF CHILDREN: Parents and caregivers are advised to oversee treatment in children

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Manufactured by:
Vapi Care Pvt. Ltd. India.
For: swiss pharma nigeria Ltd.,
5, Dopemu Road, Agege, Lagos.
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Version 1 valid as of 07/08