

PACKAGE LEAFLET: INFORMATION FOR THE USER

METFORMIN TABLETS BP 500 mg-METCHECK

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- You must contact a doctor if your symptoms worsen or do not improve after 7 days
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4

What is in this leaflet

1. What METFORMIN TABLETS BP 500 mg is and what it is used for
2. What you need to know before you use METFORMIN TABLETS BP 500 mg
3. How to use METFORMIN TABLETS BP 500 mg
4. Possible side effects
5. How to store METFORMIN TABLETS BP 500 mg
6. Contents of the pack and other information

1. What METFORMIN TABLETS BP 500 mg is and what it is used for

Non-insulin dependent diabetes when diet has failed and especially if the patient is overweight. Metformin Hcl Tablets can be given alone as initial therapy, or can be administered in combination with a sulphonylurea. In insulin-dependent diabetes, Metformin Hcl Tablets may be given as an adjuvant to patients whose symptoms are poorly controlled.

2. What you need to know before you use METFORMIN TABLETS BP 500 mg

Do not use METFORMIN TABLETS BP 500 mg

- Sensitivity to metformin hydrochloride. Diabetic coma and ketoacidosis, impairment of renal function, chronic liver disease, cardiac failure and recent myocardial infarction. History of, or states associated with, lactic acidosis such as shock or pulmonary insufficiency, alcoholism (acute or chronic), and conditions associated with hypoxemia. Pancreatitis.

Warnings and precautions

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Pregnancy, breast-feeding and fertility

- The use of Metformin Hcl Tablets during pregnancy is not advised. There is no information available concerning the safety of Metformin Hcl Tablets during lactation.

3. How to use METFORMIN TABLETS BP 500 mg

It is important that Metformin Hcl Tablets be taken in divided doses with meals.

Initially, one 850 mg tablet twice a day or one 500 mg tablet three times a day, with or after food. Good diabetic control may be achieved within a few days, but it is not usual for the full effect to be delayed for up to two weeks. If control is incomplete a cautious increase in dosage to a maximum of 3 g daily is justified.

Once control has been obtained it may be possible to reduce the dosage of Metformin Hcl Tablets.

Children: Metformin Hcl Tablets is not recommended for use.

Elderly: Metformin Hcl Tablets is indicated in the elderly, but not when renal function is impaired.

Combination therapy - see "Special Precautions"

Gastro-intestinal adverse effects with anorexia, nausea and vomiting. Metallic taste. Lactic acidosis has been associated with Metformin Hcl but, has occurred to a greater extent in patients with contra-indications to therapy. In patients with a metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonaemia) lactic acidosis should be suspected and Metformin Hcl Tablets therapy stopped.

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

Metformin Hcl is excreted by the kidney and regular monitoring of renal function is advised in all

diabetics. Metformin Hcl therapy should be stopped 2-3 days before surgery and clinical investigations such as intravenous urography and intravenous angiography and reinstated only after control of renal function has been regained. The use of Metformin Hcl is not advised in conditions which may cause dehydration or in patients suffering from serious infections, trauma or on low calorie intake.

Patients receiving continuous Metformin Hcl therapy should have an annual estimation of Vitamin B12 levels because of reports of decreased Vitamin B12 absorption.

During concomitant therapy with a sulphonylurea, blood glucose should be monitored because combined therapy may cause hypoglycaemia. Stabilisation of diabetic patients with Metformin Hcl and insulin should be carried out in hospital because of the possibility of hypoglycaemia until the correct ratio of the two drugs has been obtained.

Reduced renal clearance of Metformin Hcl has been reported during cimetidine therapy, so a dose reduction should be considered. An interaction between Metformin Hcl and anticoagulants is a possibility and dosage of the latter may need adjustment.

Contra-indications should be carefully observed.

4. Possible side effects

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5. How to store METFORMIN TABLETS BP 500 mg

Store in a dry place below 30°C. Protect from light.

Keep the medicine out of reach of children.

6. Contents of the pack and other information

What METFORMIN TABLETS BP 500 mg contains

Sodium starch glycolate, Maize starch ,Povidone (PVP K 30),Colloidal anhydrous silica
Magnesium stearate,Isntacoat Altimate IC-AL-20001,Isopropyl alcohol, Purified water

Manufactured by:



Factory address:1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

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