Gliclazide Teva 30 mg **Modified-release Tablets** gliclazide PACKAGE LEAFLET: **INFORMATION FOR THE USER** Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

doctor or pharmacist.

the same as yours.

for

Keep this leaflet. You may need to read it

If you have any further questions, ask your

This medicine has been prescribed for you

only. Do not pass it on to others. It may

harm them, even if their signs of illness are

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

possible side effects not listed in this leaflet. See section 4. What is in this leaflet 1. What Gliclazide Teva is and what it is used

2. What you need to know before you take Gliclazide Teva 3. How to take Gliclazide Teva 4. Possible side effects How to store Gliclazide Teva

6. Contents of the pack and other information What Gliclazide Teva is and what it is used for Gliclazide Teva is a medicine that reduces

belonging to the sulfonylurea group). Gliclazide Teva is used in a certain form of diabetes (type 2 diabetes mellitus) in adults, when diet, exercise and weight loss alone do not have an adequate effect on keeping blood sugar at the correct level.

blood sugar levels (oral antidiabetic medicine

take Gliclazide Teva Do not take Gliclazide Teva: • if you are allergic to gliclazide, to other medicines of the same group (sulfonylureas), to other related medicines

What you need to know before you

if you have insulin-dependent diabetes (type 1) if you have ketone bodies and sugar in your urine (this may mean you have diabetic keto-acidosis), a diabetic pre-coma or coma if you have severe kidney or liver disease if you are taking medicines to treat fungal infections (miconazole, see section 'Other

if you are breast-feeding (see section

medicines and Gliclazide Teva')

'Pregnancy and breast-feeding').

If you think any of the above situations

(sulfonamides) or any of the other

section 6)

ingredients of this medicine (listed in

applies to you, tell your doctor or pharmacist. Warnings and precautions Talk to your doctor, pharmacist or nurse before taking Gliclazide Teva You should observe the treatment plan prescribed by your doctor to achieve proper

blood sugar levels. This means, apart from

regular tablet intake, to observe the dietary

regimen, have physical exercise and, where

monitoring of your blood (and possibly urine)

necessary, reduce weight.

During gliclazide treatment regular

sugar level and also your glycated

haemoglobin (HbA1c) is necessary. In the first few weeks of treatment the risk of having reduced blood sugar levels (hypoglycaemia) may be increased. So particularly close medical monitoring is necessary. Low blood sugar (hypoglycaemia) may occur: if you take meals irregularly or skip meals altogether if you are fasting

if you are malnourished
if you change your diet
if you increase your physical activity and carbohydrate intake does not match this increase if you drink alcohol, especially in combination with skipped meals if you take other medicines or natural remedies at the same time if you take too high uoses of general if you suffer from particular hormone if you take too high doses of gliclazide induced disorders (functional disorders of

the thyroid gland, of the pituitary gland or

if your kidney function or liver function is

If you have low blood sugar you may have

adrenal cortex)

severely decreased.

become unconscious.

the following symptoms: headache, intense hunger, nausea, vomiting, weariness, sleep disorders, restlessness, aggressiveness, poor concentration, reduced alertness and reaction time, depression, confusion, speech or visual disorders, tremor, sensory disturbances,

dizziness, and helplessness. The following signs and symptoms may also occur: sweating, clammy skin, anxiety, fast or irregular heart beat, high blood pressure, sudden strong pain in the chest that may radiate into nearby areas (angina pectoris). If blood sugar levels continue to drop you may suffer from considerable confusion (delirium), develop convulsions, lose self

control, your breathing may be shallow and your heart beat slowed down, you may

nervous system and beta blockers). If you are in stress-situations (e.g. accidents, surgical operations, fever etc.) your doctor may temporarily switch you to insulin therapy. Symptoms of high blood sugar (hyperglycaemia) may occur when gliclazide has not yet sufficiently reduced the blood sugar, when you have not complied with the

In most cases the symptoms of low blood

some form of sugar, e.g. glucose tablets,

sugar vanish very quickly when you consume

sugar cubes, sweet juice, sweetened tea. You

should therefore always carry some form of

Remember that artificial sweeteners are not

nearest hospital if taking sugar does not help

absent, less obvious or develop very slowly

or you are not aware in time that your blood

sugar level has dropped. This may happen if

medicines (e.g. those acting on the central

effective. Please contact your doctor or the

Symptoms of low blood sugar may be

you are an elderly patient taking certain

or if the symptoms recur.

sugar with you (glucose tablets, sugar cubes).

treatment plan prescribed by your doctor, if you take St John's Wort (*Hypericum* perforatum) preparations (see section 'Other medicines and Gliclazide Teva or in special stress situations. These may include thirst, frequent urination, dry mouth, dry itchy skin, skin infections and reduced performance. If these symptoms occur, you must contact

Blood glucose disturbance (low blood sugar and high blood sugar) can occur when gliclazide is prescribed at the same time than medicines belonging to a class of antibiotics called fluoroquinolones, especially in elderly patients. In this case, your doctor will remind you the importance of monitoring your blood glucose. If you have a family history of or know you glucose-6-phosphate dehydrogenase (G6PD)

have the hereditary condition deficiency (abnormality of red blood cells), lowering of the hemoglobin level and

your doctor or pharmacist.

breakdown of red blood cells (hemolytic anemia) can occur. Contact your doctor before taking this medicinal product. Cases of acute porphyria have been described with some other sulfonylurea drugs, in patients who have porphyria (inherited genetic disorders with accumulation in the

children due to a lack of data.

Other medicines and Gliclazide Teva

Tell your doctor or pharmacist if you are

taking/using, have recently taken/used or might take/use any other medicines.

sugar (oral antidiabetics, GLP-1 receptor

antibiotics (e.g. sulfonamides, clarithromycin)

medicines to treat high blood pressure or heart failure (beta blockers, ACE-inhibitors

body of porphyrins or porphyrin precursors).

Gliclazide Teva is not recommended for use in

The blood sugar lowering effect of gliclazide may be strengthened and signs of low blood sugar levels may occur when one of the following medicines is taken: other medicines used to treat high blood

agonists or insulin)

such as captopril, or enalapril) medicines to treat fungal infections (miconazole, fluconazole) medicines to treat ulcers in the stomach or duodenum (H2 receptor antagonists) medicines to treat depression (monoamine oxidase inhibitors) painkillers or antirheumatics (ibuprofen,

phenylbutazone)

medicines containing alcohol.

following medicines is taken:

The blood glucose lowering effect of

sugar levels may occur when one of the

gliclazide may be weakened and raised blood

 medicines to treat disorders of the central nervous system (chlorpromazine) medicines reducing inflammation

(corticosteroids) medicines to treat asthma, or used during

labour (intravenous salbutamol, ritodrine and terbutaline) medicines to treat breast disorders, heavy (danazol)

menstrual bleeding and endometriosis St John's Wort - Hypericum perforatum-preparations. Blood glucose disturbance (low blood sugar and

high blood sugar) can occur when a medicine belonging to a class of antibiotics called fluoroquinolones is taken at the same time than Gliclazide Teva, especially in elderly patients.

which reduce blood clotting (warfarin). Consult your doctor before you start taking another medicinal product. If you go into hospital tell the medical staff you are taking Gliclazide Teva. non-alcoholic drinks.

Gliclazide may increase the effects of medicines

Gliclazide Teva with food, drink and alcohol Gliclazide Teva can be taken with food and Drinking alcohol is not recommended as it can alter the control of your diabetes in an unpredictable manner. Pregnancy and breast-feeding If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

during pregnancy. You must **not** take Gliclazide Teva while you are breast-feeding. Driving and using machines Your ability to concentrate or react may be

impaired if your blood sugar is too low

Gliclazide Teva is not recommended for use

(hypoglycaemia), or too high (hyperglycaemia) or if you develop visual problems as a result of such conditions. Bear in mind that you could endanger yourself or others (e.g. when driving a car or using machines). Please ask your doctor whether you can drive a car if you: have frequent episodes of low blood sugar (hypoglycaemia)

have few or no warning signals of low blood sugar (hypoglycaemia).

Gliclazide Teva contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. How to take Gliclazide Teva

doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose is determined by the doctor, depending on your blood and possibly urine sugar levels. Change in external factors (e.g. weight reduction, change in life style, stress)

or improvements in the blood sugar control

The recommended starting dose is one tablet once daily. The usual dose can vary from one

to four tablets (maximum 120 mg) in a single

may require changed gliclazide doses.

Always take this medicine exactly as your

intake at breakfast time. This depends on the response to treatment. If a combination therapy of Gliclazide Teva with metformin, an alpha glucosidase inhibitor, a thiazolidinedione, a dipeptidyl peptidase-4 inhibitor, a GLP-1 receptor agonist or insulin is initiated your doctor will determine the proper dose of each medicine individually for you.

If you notice that your blood sugar levels are

high although you are taking the medicine as

prescribed, you should contact your doctor or

pharmacist.

should

or drink.

case of emergency.

Routes and method of administration Swallow your tablets whole with a glass of water whilst having your breakfast, preferably at the same time each day. Do not chew the tablets. You must always eat a meal after taking your tablet(s). It is important not to skip a meal when you are on Gliclazide Teva.

If you take more Gliclazide Teva than you

If you take too many tablets contact your

doctor or the nearest hospital Accident &

Emergency department immediately. The signs of overdose are those of low blood

sugar (hypoglycaemia) described in Section 2.

The symptoms can be helped by taking sugar

(4 to 6 lumps) or sugary drinks straight away, followed by a substantial snack or meal. If the patient is unconscious immediately inform a doctor and call the emergency services. The

same should be done if somebody, e.g. a

child, has taken the product unintentionally.

It should be ensured that there is always a

pre-informed person that can call a doctor in

Unconscious patients must not be given food

If you forget to take Gliclazide Teva It is important to take your medicine every day as regular treatment works better. If you forget to take a dose, take the next dose at the usual time. **Do not** take a double dose to make up for a forgotten tablet.

As the treatment for diabetes is usually life

long, you should discuss with your doctor before stopping this medicine. Stopping

(hyperglycaemia) which increases the risk of

developing complications of diabetes.

If you stop taking Gliclazide Teva

could cause high blood sugar

If you have any further questions on the use of this medicine, ask your doctor or pharmacist. A Possible side effects

Like all medicines, this medicine can cause side

effects, although not everybody gets them.

experience any of the following symptoms

Rare (may affect up to 1 in 1,000 people):

breathing difficulty) have been reported. The rash may progress to widespread blistering or peeling of the skin. If you

Tell your doctor immediately if you

Skin reactions such as rash, redness, itching, hives, angioedema (rapid swelling of the tissue such as eyelids, face lips, mouth, tongue or throat that may result in

develop this, stop taking Gliclazide Teva, seek urgent advice from a doctor and tell him that you are taking this medicine. Exceptionally, signs of severe hypersensitivity reactions (DRESS) have been reported: initially as flu-like symptoms

rash with high temperature. Abnormal liver function tests, changes in your liver (which can cause yellow skin and eyes). If you get this, see your doctor immediately. These effects generally disappear if the medicine is stopped. Your doctor will decide

whether to stop your treatment.

and a rash on the face then an extended

For symptoms and signs of hypoglycaemia see section 2 'Warnings and precautions'. If left untreated these symptoms could progress to drowsiness, loss of

Not known (frequency cannot be estimated

Severe hypoglycaemia (low blood sugar).

from the available data):

consciousness or possibly coma. If an episode of low blood sugar is severe or prolonged, even if it is temporarily controlled by eating sugar, you should seek immediate medical attention. As for other sulfonylureas, the following adverse events have been observed: cases of severe changes in the number of blood cells

and allergic inflammation of the wall of blood vessels, reduction in blood sodium (hyponatraemia), symptoms of liver impairment (e.g. jaundice) which in most cases disappeared after withdrawal of the sulfonylureas, but may lead to life-threatening liver failure in isolated cases. Other possible side effects Common (may affect up to 1 in 10 people):

'Warnings and precautions'. Uncommon (may affect up to 1 in 100 people): Gastrointestinal disturbances including

Hypoglycaemia (low blood sugar). For

symptoms and signs see section 2

abdominal pain, nausea, vomiting, indigestion, diarrhoea, constipation. These effects are reduced when Gliclazide Teva is taken with a meal as recommended.

Rare (may affect up to 1 in 1,000 people):

Decrease in the number of cells in the blood (e.g. platelets, red and white blood cells) which may cause paleness, prolonged bleeding, bruising, sore throat and fever have been reported. These symptoms usually vanish when the treatment is discontinued.

Your vision may be affected for a short time

is due to changes in blood sugar levels.

If you get any side effects, talk to your doctor,

possible side effects not listed in this leaflet.

You can also report side effects directly via

How to store Gliclazide Teva

Keep this medicine out of the sight and reach

Do not use this medicine after the expiry date

These effects generally disappear if the

pharmacist or nurse. This includes any

especially at the start of treatment. This effect

the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on

the safety of this medicine.

medicine is stopped.

Reporting of side effects

which is stated on the blister, the tablet container and the carton after EXP. The expiry

of children.

date refers to the last day of that month. Store below 25°C.

protect the environment.

information

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

Contents of the pack and other

What Gliclazide Teva contains The active substance is gliclazide. Each modified-release tablet contains 30 mg gliclazide.

carbonate, colloidal anhydrous silica,

What Gliclazide Teva looks like and contents

The modified-release tablets are white, oval,

of 10, 14, 20, 28, 30, 56, 60, 84, 90, 100, 120 or

The other ingredients are lactose monohydrate, hypromellose, calcium

biconvex tablets. Gliclazide Teva is available in blisters in boxes

magnesium stearate.

of the pack

Manufacturer

PL 00289/2513

180 tablets and in tablet containers of 90, 120 or 180 tablets.

Not all pack sizes may be marketed.

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