

GLITROL CONTROLLED RELEASED CAPSULES

Gliclazide (30mg)

What is in this leaflet

- What Glitrol CR 30 is used for
- How Glitrol CR 30 works
- Before you take Glitrol CR 30
- How to take Glitrol CR 30
- While you are using Glitrol CR 30
- Side effects
- Storage and Disposal of Glitrol CR 30
- Product Description
- Manufacturer and Product Registration Holder
- Date of Revision

What GLITROL CR 30 is used for

GLITROL CR 30 is used to control blood glucose (sugar) in patients with Type II diabetes mellitus. This type of diabetes is also known as non-insulin dependent diabetes (NIDDM), or maturity-onset diabetes.

How GLITROL CR 30 Works

Glucose is used by the body as fuel, and all people have glucose circulating in their blood. In diabetes, levels of blood glucose are higher than is needed, which is also known as hyperglycaemia.

If your blood glucose is not properly controlled, you may experience hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose). High blood glucose can lead to serious problems with our heart, circulation and/or kidneys.

It is very important to control high blood glucose whether or not you feel unwell. This really helps to avoid serious long-term health problems, which can involve the heart, eyes, circulation, and/or kidneys.

A section at the end of this leaflet contains advice about recognizing and treating hyperglycaemia.

GLITROL CR 30 is used when diet and exercise are not enough to control your blood glucose properly.

It lowers blood glucose by increasing the amount of insulin (a hormone that controls blood glucose levels) produced by your pancreas.

As with many medicines used for the treatment of diabetes, there is a possibility that blood glucose levels may become very low during treatment with GLITROL CR 30. This is known as hypoglycaemia.

GLITROL CR 30 is available only with a doctor's prescription. GLITROL CR 30 is not addictive. Ask your doctor if you have any questions about why GLITROL CR 30 has been prescribed for you.

Before you take GLITROL CR 30

There are some people who should not take GLITROL CR 30. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor, pharmacist, or diabetes educator.

When you must not take it

Do not take GLITROL CR 30 if you have an allergy to:

- GLITROL CR 30
- sulfonylureas
- related medicines such as sulfa antibiotics or to thiazide diuretics (a type of "fluid" or "water" tablet).
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to these medicines may include:

- skin rash
- itching or hives

If you are not sure if you have an allergy to GLITROL CR 30, check with your doctor.

Do not take GLITROL CR 30 if you have or have had any of the following medical conditions:

- Type 1 diabetes mellitus (also known as insulin-dependent diabetes (NIDDM), or juvenile onset diabetes).
- unstable diabetes
- you have diabetic ketoacidosis (a problem which affects the acidity of your blood and can lead to coma - which is mainly associated with Type 1 diabetes).

- severe kidney disease
- severe liver disease

If you are not sure if you have any of the above, ask your doctor.

Do not take GLITROL CR 30 if you are pregnant or intend becoming pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will usually replace GLITROL CR 30 with insulin while you are pregnant.

Do not take GLITROL CR 30 if you are breastfeeding or plan to breast-feed.

GLITROL CR 30 is not recommended while you are breastfeeding. It is not known whether GLITROL CR 30 passes into breast milk.

Do not give GLITROL CR 30 to a child.

There is no experience with the use of GLITROL CR 30 in children.

Elderly people can generally use GLITROL CR 30 safely.

There are no special instructions for older people taking GLITROL CR 30 .

Do not take GLITROL CR 30 after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take GLITROL CR 30 if the packaging is torn or shows signs of tampering.

If it is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking GLITROL CR 30 , talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

GLITROL CONTROLLED RELEASED CAPSULES

Gliclazide (30mg)

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have had any of the following medical conditions:

- kidney disease
- liver disease
- a history of diabetic coma.
- adrenal, pituitary or thyroid problems
- heart failure

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hyperglycaemia - for example:

- you are ill or feeling unwell (especially with fever or infection)
- you are injured
- you are having surgery.
- you are taking less GLITROL CR 30 than prescribed
- you are taking less exercise than normal
- you are eating more carbohydrate than normal.

Tell your doctor if you have any medical condition, or do anything, that may increase the risk of hypoglycaemia - for example:

- drinking alcoholic drinks.
- not eating regular meals.
- taking more exercise than usual.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor, pharmacist or diabetes educator about any of the above, tell them before you start taking GLITROL CR 30 .

Taking other medicines

Tell your doctor, pharmacist or diabetes educator if you are taking any other medicines, including medicines you buy without a

prescription from a pharmacy, supermarket or health food shop.

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood-glucose lowering effect of GLITROL CR 30.

These include:

- other medicines used to treat diabetes (tablets and insulin)
- some medicines used to treat high blood pressure and other heart conditions
- some hormones used in hormone replacement therapy and oral contraceptives
- some medicines for depression and other mental illness
- some medicines for epilepsy
- some medicines for high triglyceride levels
- some medicines used to treat arthritis, pain and inflammation
- some antibiotics some medicines used to treat fungal or yeast infections
- some medicines used to prevent blood clots (warfarin and similar medicines)
- some medicines used to treat acid reflux and stomach ulcers
- some steroid medicines.
- some medicines for hormonal disturbances (such as danazol)
- some medicines for asthma

You may need different amounts of your medicine or you may need to take different medicines. Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking GLITROL CR 30 .

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to Take GLITROL CR 30

Follow all directions given to you by your doctor, pharmacist, and diabetes educator carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many Capsules to take each day. They may increase or decrease the dose, depending on your blood glucose levels.

The daily dose may vary between 1 and 4 Capsules per day, i.e. from 30 to 120 mg taken orally, once daily.

It is recommended that the Capsule(s) be taken at breakfast time.

When to take it

Swallow the Capsule with a glass of water. GLITROL CR 30 Capsules should be swallowed whole.

It is important to take your GLITROL CR 30 at the same time each day - usually with breakfast.

Taking GLITROL CR 30 with food can help to minimise the risk of hypoglycaemia.

Do not skip meals while taking GLITROL CR 30.

How long to take it

Continue taking GLITROL CR 30 for as long as your doctor recommends. Make sure you keep enough GLITROL CR 30 to last over weekends and holidays.

GLITROL CR 30 will help control your diabetes but will not cure it. Therefore, you may have to take it for a long time.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as you remember (with food), then go back to taking your capsules as you would normally. Missed doses can cause high blood glucose (hyperglycaemia) If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose you have missed.

GLITROL CONTROLLED RELEASED CAPSULES

Gliclazide (30mg)

If you double a dose, this may cause low blood glucose (hypoglycaemia)

If you take too much (overdose)

You may need urgent medical attention. If you take too much GLITROL CR 30 together with other medicines for diabetes or alcohol, you may experience symptoms of low blood glucose hypoglycaemia).

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and fitting. At the first signs of hypoglycaemia, raise your blood glucose quickly by following the boxed instructions at the end of this leaflet. If you experience any of these symptoms, immediately get medical help.

While you are using GLITROL CR 30

Things you must do

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking GLITROL CR 30.

If you are about to start taking any new medicines, tell you doctor and pharmacist that you are taking GLITROL CR 30. Take GLITROL CR 30 exactly as your doctor has prescribed.

Otherwise you may not get the full benefits from treatment.

Make sure you check your blood glucose levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

Instructions at the end of this leaflet can help you with this.

Visit your doctor regularly so that they can check on your progress. Carefully follow your doctor's and

dietitian's advice on diet, drinking alcohol and exercise.

Tell your doctor immediately if you notice the return of any symptoms of hyperglycaemia that you had before starting GLITROL CR 30.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision. These may be signs that GLITROL CR 30 is no longer working, even though you may have been taking it successfully for some time.

Things you must not do

Do not give GLITROL CR 30 to anyone else, even if they have the same condition as you.

Do not use GLITROL CR 30 to treat other complaints unless your doctor tells you to.

Do not stop taking GLITROL CR 30, or change the dosage, without checking with your doctor.

Do not skip meals while taking GLITROL CR 30.

Things to be careful of

If you drink alcohol while taking GLITROL CR 30, you may get flushing, headache, breathing difficulties, rapid heart beat, stomach pains or feel sick and vomit.

Be careful driving or operating machinery until you know how GLITROL CR 30 affects you.

Also, be especially careful not to let your blood glucose levels fall too low.

GLITROL CR 30 may cause dizziness and drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous. If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes

- carry some form of sugar to treat hypoglycaemia if it occurs, for example, sugar sachets or jelly beans

- carry emergency food rations in case of a delay, for example, dried fruit, biscuits or muesli bars

- keep GLITROL CR 30 readily available

If you become sick with a cold, fever or flu, it is very important to continue taking GLITROL CR 30, even if you fell unable to eat your normal meal. If you have trouble eating solid food, you can eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

Side effects

HYPOGLYCAEMIA

As for other sulphonylureas, treatment with GLITROL CR 30mg can cause hypoglycaemia, if mealtimes are irregular and, in particular, if meals are skipped. Possible symptoms of hypoglycaemia are: headache, intense hunger, nausea, vomiting, lassitude, drowsiness, sleep disorders, agitation, aggression, poor concentration, reduced awareness and slowed reactions, depression, confusion, visual and speech disorders, aphasia, tremor, paresis, sensory disorders, dizziness, feeling of powerlessness, loss of self-control, delirium, convulsions, shallow respiration, bradycardia, drowsiness and loss of consciousness, possibly resulting in coma and lethal outcome. In addition, signs of adrenergic counter-regulation may be observed:

sweating, clammy skin, anxiety, tachycardia, hypertension, palpitations, angina pectoris and cardiac arrhythmia. Usually, symptoms disappear after intake of carbohydrates (sugar). However, artificial sweeteners

GLITROL CONTROLLED RELEASED CAPSULES

Gliclazide (30mg)

have no effect. Experience with other sulphonylureas shows that hypoglycaemia can recur even when measures prove effective initially.

If a hypoglycaemic episode is severe or prolonged, and even if it is temporarily controlled by intake of sugar, immediate medical treatment or even hospitalisation are required.

The following undesirable effects have been more rarely reported:

- Skin and subcutaneous tissue disorders: rash, pruritus, urticaria, erythema, maculopapular rashes, bullous reactions.

Allergic vasculitis has been reported in very rare cases for other sulphonylureas.

- Blood and lymphatic system disorders: Changes in haematology are rare.

- Hepato-biliary disorders: raised hepatic enzyme levels (AST, ALT, alkaline phosphatase), hepatitis (isolated reports). Discontinue treatment if cholestatic jaundice appears.

- Eye disorders

Transient visual disturbances may occur especially on initiation of treatment, due to changes in blood glucose levels.

Like all medicines Glitrol CR 30 can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of GLITROL CR 30

Storage

Keep your capsules in the pack until it is time to take them.

GLITROL CR 30 will not keep as well outside its blister packaging.

Keep them in a cool dry place where the temperature stays below 25^o C.

Do not store medicines in the bathroom or near a sink. Do not leave them in a car or on a window sill.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking GLITROL CR 30, or the capsules have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

Product Description

What it looks like

GLITROL CR 30 containing white to off white spherical to oval pellets. The capsule has light blue cap and ivory body.

Ingredients

Active ingredient

Gliclazide. Each Controlled release Capsule contains 30 mg of Gliclazide.

Inactive ingredients

Non pareil seeds, Starch, Purified Talc, Hypromellose, Povidone, Polyacrylate dispersion 30 %, Purified water.

Approved colors used in capsule shell

MAL Number :

MAL No.: MAL12030004A

Manufacturer

Inventia Healthcare Pvt. Ltd.

F1, F1/1 Additional Ambernath, MIDC, Ambernath (E), Dist. Thane – 421506 India

Product Registration Holder

Healol Pharmaceuticals SDN.BHD

74-3, Jalan 1/27F, KLSC, Wangsa Maju, Kuala Lumpur, Malaysia

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