

GLIT 15 (PIOGLITAZONE TABLETS 15MG)

GLIT 30 (PIOGLITAZONE TABLETS 30MG)

Pioglitazone hydrochloride (15mg, 30mg)

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What GLIT is used for

- GLIT is used as oral monotherapy in type 2 diabetes mellitus patients, particularly overweight patients whom are inadequately controlled by diet and exercise and where metformin cannot be tolerated.
- GLIT is used for oral combination treatment in type 2 diabetes mellitus patients with insufficient glycaemic control despite maximal tolerated dose of oral monotherapy with either metformin or sulfonylurea.

How GLIT works

GLIT is a thiazolidinedione antidiabetic agent that depends on the presence of insulin for its mechanism of action. It acts primarily by decreasing insulin resistance. It decreases insulin resistance in the body, resulting in increased insulin-dependent glucose disposal and decreased liver glucose output.

Before you use GLIT

- When you must not use it

Do not use GLIT if you are:

- a) Hypersensitive to pioglitazone or to any of the excipients of the tablet listed at the end of this leaflet.
- b) Having heart failure or history of heart failure (all stages).
- c) A patient of reduced liver

function.

- d) Pregnant or breastfeeding.
- e) A type 1 diabetes patient.
- f) A bladder cancer patient or have a history of bladder cancer.
- g) Having blood in your urine.

- Before you start to use it

- You must undergo blood tests for liver function prior to the start of therapy, and periodically thereafter per clinical judgment of the health care professional.
- Talk to your doctor if you are pregnant.

- Taking other medicines

- GLIT can be co-administered with:
 - a) Oral contraceptives
 - b) Fexofenadine HCl
 - c) Glipizide
 - d) Digoxin
 - e) Warfarin
 - f) Metformin
 - g) Midazolam
 - h) Ranitidine HCl
 - i) Nifedipine ER
 - j) Ketoconazole
 - k) Atorvastatin Calcium
 - l) Theophylline
 - m) Cytochrome P450

Tell your doctor if you are taking any of the following medicines:

- a) Medicine containing insulin
- b) Medicine containing oral hypoglycemic agents

This is because the combination therapy with either one of the above medicines may cause the risks of hypoglycemia.

How to use GLIT

- How much to use

You may start with 15mg or 30mg once daily. The dose may be increased in increments up to 45mg once daily.

Use in the elderly, no dosage

adjustment is necessary for elderly patients.

Use in children, GLIT is not recommended in patients under 18 years old.

Use in impaired renal function, no dosage adjustment is necessary.

Use in pregnancy, there are no adequate and well-controlled studies in pregnant women. Discuss with your doctor before taking GLIT.

- When to use it

GLIT should be taken orally, once daily with or without meals.

- How long to use it

Continue using GLIT for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it's almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- You must adhere to dietary instructions from your doctor and have blood glucose and glycosylated hemoglobin tested regularly. During periods of stress such as fever, trauma,

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infection, or surgery, medication requirements may change and patients should be reminded to seek medical advice promptly.

- If you experience an unusually rapid increase in weight or edema or develop shortness of breath or other symptoms of heart failure while on GLIT, you should immediately report these symptoms to your doctor.
- You should seek immediate medical advice for unexplained nausea, vomiting, abdominal pain, fatigue, anorexia or dark urine.
- Patients may be at an increased risk for pregnancy while taking GLIT.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give GLIT to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

GLIT can cause fluid retention. Fluid retention may lead to or exacerbate heart failure. You should talk to your doctor if there is any deterioration in cardiac status.

Side effects

Like all medicines, GLIT can cause side effects, although not everybody gets them.

The side effects of GLIT are listed as below:

- Upper respiratory tract infection
- Headache
- Sinusitis
- Myalgia
- Tooth disorder
- Diabetes mellitus aggravated
- Pharyngitis

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 visiting the website npra.gov.my [Consumers > Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of GLIT

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light and moisture

Do not use GLIT after the expiry date which is printed on the carton.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

GLIT 15 (Pioglitazone Tablets 15mg)
- White to off white, round, biconvex, uncoated tablets embossed "15" on one side and plain on other side.

GLIT 30 (Pioglitazone Tablets 30mg)
- White to off white, round, flat, beveled edged, uncoated tablets embossed "30" on one side and plain on the other side.

- Ingredients

- Active ingredient:

Pioglitazone hydrochloride

- Inactive ingredients

Lactose Monohydrate, Carmellose Calcium, Hydroxypropyl Cellulose-L & Magnesium Stearate

MAL number:

GLIT 15 - MALxxxAZ

GLIT 30 - MALxxxAZ

Manufacturer

Ind-Swift Limited, Off NH 21, Village Jawaharpur, Tehsil Derabassi, District SAS Nagar (Mohali) Punjab, 140507 India

Product Registration Holder

Synerrv Sdn Bhd, SO-29-2, Menara 1, KL Eco City, Jalan Bangsar, Kg. Haji Abdullah Hukum, 59200 Kuala Lumpur Malaysia

Date of revision

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