DIPAZIDE®

Glipizide 5mg

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What DIPAZIDE® is used for

DIPAZIDE® is used to control blood sugar in patients with Type II diabetes mellitus, in addition to diet and exercise. This type of diabetes is also known as non-insulindependent diabetes mellitus (NIDDM).

DIPAZIDE® is used when diet and exercise are insufficient to control blood sugar (glucose). This medicine is only available with a doctor's prescription.

How DIPAZIDE® works

DIPAZIDE® belongs to a class of medicines called sulphonylureas. This class of medicine lower high blood glucose by increasing the amount of insulin produced by your pancreas.

Uncontrolled blood glucose may lead to hypoglycaemia (low blood glucose) or hyperglycaemia (high blood glucose). Hyperglycaemia may result in serious problems with your heart, eyes, circulation or kidneys.

Signs of hypoglycaemia may include the following:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- crying
- irritability
- hunger
- numbness around the lips and tongue

Signs of hyperglycaemia may include the following:

- lethargy or tiredness
- headache
- thirst
- passing large amounts of urine
- blurred vision

Before you use DIPAZIDE®

When you must not use it

Do not take DIPAZIDE® if you are allergic to:

- DIPAZIDE® and other medicines containing glipizide
- other sulphonylureas
- sulfur antibiotics (e.g. sulphonamides) or thiazide diuretics (eg. chlorothiazide)
- any of the ingredients listed under the <u>Ingredients</u> section of this leaflet.

Skin rash and itching may be a symptom of an allergic reaction to DIPAZIDE®.

Do not take DIPAZIDE® if you have any of the following conditions:

- Type I diabetes mellitus (insulin dependent diabetes mellitus)
- diabetes ketoacidosis with or without coma
- severe kidney disease
- severe liver disease

Do not take DIPAZIDE® if:

- you are pregnant or intend on becoming pregnant.
- you are breast-feeding or plan to breast-feed.
- the packaging is torn or shows signs of tampering or the tablets do not look quite right.
- the expiry date (Exp.) on the carton has passed.

Do not give DIPAZIDE® to children. Please consult your healthcare professional if you are unsure about any of the above.

Before you start to use it

Please inform your healthcare professional regarding the following:

- a) If you are allergic to any other medicines or any other substances such as foods, preservatives or dyes.
- b) If you have or have had any of the following conditions:
- kidney problems
- liver problems
- adrenal or pituitary or severe thyroid disease
- hemolytic anaemia or G6PD deficiency (a condition where the body does not have enough of the enzyme glucose-6phosphate dehydrogenase)
- c) If you ever drink alcohol
- d) If you do not have regular meals
- e) If you exercise heavily
- f) If you are feeling ill or unwell

Taking other medicines

Tell your healthcare professional if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food

shop. DIPAZIDE® may interfere with some medicines.

- a) Some medicines may result in hypoglycaemia by increasing the bloodglucose-lowering effect of DIPAZIDE®. These include:
- alcohol
- certain medicines for heart conditions or high blood pressure (beta-blockers)
- certain medicines for arthritis, pain and inflammation (salicylates eg. aspirin)
- certain antibiotics (sulphonamides, chloramphenicol)
- medicines for preventing blood clots (coumarin derivatives)
- probenecid (a medicine for gout or to increase the blood levels of some antibiotics)
- certain medicines for depression (monoamine oxidase inhibitors)
- certain medicines for cancer (cyclophosphamide)
- b) Some medicines may result in loss of your diabetes control by weakening the blood glucose-lowering effect of DIPAZIDE®.
 These include:
- alcohol
- corticosteroids such as prednisone and cortisone
- certain hormonal treatments for birth control, Hormone Replacement Therapy (HRT) or other women's health problems.
 Examples include oestrogens, progestogens, oral contraceptives and danazol.
- diuretics/fluid tablets (thiazides)

A more complete list of medicines to be careful with or avoid while taking DIPAZIDE® can be obtained

from your healthcare professional.

How to use DIPAZIDE®

How much to use

Your doctor will recommend how many tablets to take daily. The usual starting dose is half to 1 tablet taken 30 minutes before breakfast. However, a lower starting dose may be needed in older people or those with liver problems.

Your doctor may increase or decrease the dose depending on your blood glucose levels.

When to use it

DIPAZIDE® should be taken approximately half an hour before meals. Swallow the tablets whole with a glass of water. Your doctor may recommend that you take the tablet(s) just once a day or may divide the dose so that it is given more than once a day.

How long to use it

DIPAZIDE® should be continued for as long as your doctor recommends.

DIPAZIDE® helps your diabetes control but will not cure it.

If you forget to use it

Skip the missed dose if it is almost time for your next dose and take your next dose when you are supposed to.

Otherwise, take it as soon as you remember, then go back to taking your tablets as you normally do.

Missed doses can cause hyperglycaemia. Do not double the dose to make up for the missed dose.

Check with your healthcare professional if you are unsure of what to do or if you miss more than one dose.

If you use too much (overdose)

Immediately inform your doctor or the National Poison Centre for advice if you suspect that you or anyone else may have taken too much DIPAZIDE®.

The National Poison Centre can be contacted at:

- 1-800-88-8099 during office hours
- +6012-430 9499 after office hours

Alternatively, go to your nearest hospital. Do this even if you are not experiencing signs of discomfort or poisoning as you may need urgent medical attention.

Taking too much DIPAZIDE® may result in hypoglycaemia symptoms. At the first signs of hypoglycaemia, raise your blood glucose quickly by taking sugar, honey or a non-diet soft drink.

If not treated quickly, these symptoms may progress to loss of coordination, slurred speech, loss of consciousness and fitting. Seek immediate medical attention if any of these symptoms occur.

While you are using DIPAZIDE®

Things you must do

Tell your healthcare professional if you become pregnant or if you are going to begin any new medicines.

Make sure that you, friends and family recognise the symptoms of hypoglycaemia and

hyperglycaemia and know how to treat them.

Hypoglycaemia risk is increased in the elderly or in people who take other diabetes medicines such as insulin or metformin.

Contact your doctor immediately if you experience any hyperglycaemia signs.

The following situations increase the risk of hyperglycaemia:

- undiagnosed or uncontrolled diabetes
- illness, injury, infection or
- too little DIPAZIDE®
- too little exercise
- eating more carbohydrate than normal

Check your blood glucose levels regularly as this is the best way to determine if your diabetes is well controlled.

Immediately inform your doctor if you notice the return of any symptoms you had before starting DIPAZIDE®.

Things you must not do

Do not stop taking DIPAZIDE® or alter the dose without checking with your doctor. Do not skip meals while taking DIPAZIDE®.

Things to be careful of

Please inform your healthcare professional that you are taking DIPAZIDE® if you:

- will be undergoing major surgery
- experience severe trauma
- experience infection, high temperature or gangrene
- experience severe or unstable diabetes

DIPAZIDE® may result in dizziness and drowsiness. Low blood glucose levels may also

slow your response time and affect ability to operate machinery or drive.

Drinking alcohol while taking DIPAZIDE® may make you feel sick, have a headache, stomach pains, flushing, breathing difficulties or rapid heartbeat.

Sick days

Continue taking DIPAZIDE® even if you feel unable to eat your normal meal when you become sick with a cold, fever or flu. If you have difficulties eating solid food, use sugarsweetened drinks as a carbohydrate substitute, or eat small amounts of bland food.

Please consult your healthcare professional for a list of foods for sick days.

Side effects

All medicines can have side effects which are occasionally serious.

Inform your healthcare professional if you notice any of the following:

- of hypoglycaemia signs which may include weakness, trembling or shaking, sweating, lightheadedness, headache, dizziness, irritability, tearfulness crying, or lack hunger and concentration
- confusion, shaking and feeling generally unwell.
- stomach upset including nausea, vomiting and stomach cramps or pain.
- diarrhoea or constipation
- rashes, sores, redness, itching, or eczema.
 Sometimes these effects may disappear following continued treatment but consider asking for advice

if you experience skin problems.

Inform your healthcare professional immediately or go to your nearest hospital if you experience any of the following:

- yellowing of the skin or eyes (also called jaundice).
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin.
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- signs of anaemia such as tiredness, being short of breath and looking pale.
- signs of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin or eyes, and dark coloured urine.

This is not a complete list of all possible side effects. Please consult your healthcare professional for further information.

You may report any side effects or adverse drug reactions 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 DIPAZIDE®

Storage

- Keep tablets away from children in a place where they cannot reach
- Keep tablets in the blister pack until you consume them as the packaging protects the tablets.
- Keep the pack in a cool, dry place below 30°C.

 Keep away from heat and dampness as these can destroy some medicines.

Disposal

Consult your healthcare professional for disposal of leftover tablets that have passed their expiry date or if you have been instructed to stop the medicine.

Product Description

What it looks like

DIPAZIDE® tablets are white, round and biconvex with

on one side. They are

scored on the other side so that they can be broken in half. Each pack contains 100 tablets in blister strips.

Ingredients

Active ingredient: 5 milligrams of glipizide in each DIPAZIDE® tablet.

Inactive ingredients:
Microcrystalline cellulose, lactose, sodium starch glycolate and magnesium stearate.

MAL number: MAL19992691A

Manufacturer

Siam Bheasach Co., Ltd.,

123 Soi Chokechairuammitr, Vibhavadi-Rangsit Road, Chatuchak, Bangkok 10900 and 9 Soi Chokechairuammitr 3, Vibhavadi-Rangsit Road, Dindang, Bangkok 10400, Thailand.

Product Registration Holder

SPG Pharma (Malaysia) Sdn. Bhd., Suite 1701, Block A, Damansara Intan e-Business Park, No. 1, Jalan SS20/27, 47400 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

21/03/2014