

Daonil(R)

(DAY-o(h)-nill)

glibenclamide (glib-EN-clam-IDE)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Daonil. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Daonil against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor, pharmacist or diabetes educator.

Keep this leaflet with the medicine.

You may need to read it again.

What Daonil is used for

Daonil is used to control blood glucose levels in patients with type 2 diabetes mellitus. This type of diabetes is also known as non-insulin-dependent diabetes (NIDDM) or maturity onset diabetes.

Daonil is used in conjunction with diet control and exercise to control blood sugar.

Daonil can be used alone, or in combination with insulin or other anti-diabetes medicines.

How Daonil works

Daonil lowers high blood glucose by increasing the amount of insulin released by your pancreas.

Daonil belongs to a group of medicines called sulphonylureas.

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 your heart, eyes, circulation or kidneys.

Low blood glucose can occur suddenly. Signs may include:

- * weakness, trembling, shaking
- * sweating
- * light headedness, dizziness, headache or lack of concentration
- * tearfulness, crying or depression
- * irritability
- * hunger
- * numbness around the lips and tongue
- * restlessness or disturbed sleep

If not treated promptly, these may progress to:

- * loss of co-ordination
- * slurred speech
- * confusion
- * loss of consciousness or seizures

High blood glucose usually occurs more slowly than low blood glucose. Signs of high blood glucose may include:

- * lethargy or tiredness
- * headache
- * severe thirst

- * passing large amounts of urine and more often
- * blurred vision
- * dry mouth or dry skin

This medicine is available only with a doctor's prescription.

Daonil is not addictive.

Before you take Daonil

When you must not take it

Do not take Daonil if:

- **You have an allergy to:**

- * Daonil or related medicines (such as sulphur antibiotics or sulphonylureas)
- * any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to this medicine may include itching or rash.

If you are not sure if you have or have had an allergic reaction to Daonil check with your doctor.

- **You have any of the following conditions:**

- * type 1 diabetes mellitus (insulin-dependent diabetes mellitus, also known as IDDM, or juvenile or growth onset diabetes)
- * unstable diabetes
- * diabetic ketoacidosis
- * diabetic coma or pre-coma
- * severe kidney disease
- * severe liver disease

- * you are taking bosentan
- * glucose-6-phosphate dehydrogenase (G6PD) deficiency

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

- **You are pregnant or intend to become pregnant.**

Insulin is more suitable for controlling blood sugar during pregnancy. Your doctor will replace Daonil with insulin while you are pregnant.

- **You are breastfeeding or planning to breastfeed.**

It is not known if Daonil passes into breast milk. Daonil should not be taken while you are breastfeeding

- **The packaging is torn or shows signs of tampering (or the tablets do not look quite right).**
- **The expiry date on the pack has passed.**

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

If you are not sure whether you should start taking Daonil, talk to your doctor.

Do not give Daonil to children.

There is not enough information to recommend the use of Daonil in children.

Before you start to take it

Tell your doctor if:

- **You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.**
- **You are breastfeeding or plan to breastfeed.**

It is not known whether glibenclamide is excreted in milk or whether it has a harmful effect on the newborn. Therefore it is not recommended for nursing mothers unless the expected benefits outweigh any potential risks.

- **You have or have had any of the following medical conditions:**

- * kidney problems
- * liver problems
- * a history of diabetic coma
- * adrenal, pituitary (or thyroid) problems
- * heart failure

- **You drink alcohol in any amount.**

- **You do not eat regular meals.**

- **You do a lot of exercise or heavy work.**

- **You are feeling ill or unwell.**

Diet, exercise, alcohol and your general health all strongly affect the control of your diabetes. Discuss these things with your doctor.

- **You are taking any other antidiabetic treatment.**

If you have not told your doctor about any of the above, tell them before you start to take Daonil.

Taking other medicines

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

Some medicines may lead to low blood glucose (hypoglycaemia) by increasing the blood glucose lowering effect of Daonil.

These include:

- * alcohol
- * some medicines used to treat high blood pressure
- * some medicines used to treat arthritis, pain and inflammation
- * (anabolic) steroids
- * some cholesterol-lowering medicines
- * other medicines used to treat diabetes
- * some antibiotics
- * medicines used to prevent blood clots
- * disopyramide; a medicine used to treat irregular heart rhythms

- * some medicines used to treat depression
- * oxpentifylline, a medicine used to treat blood vessel problems
- * some medicines used to treat cancer
- * some medicines used to treat gout
- * cimetidine and ranitidine, medicines used to treat reflux and ulcers

Some medicines may lead to loss of control of your diabetes (resulting in high blood glucose) by weakening the blood glucose-lowering effect of Daonil.

These include:

- * alcohol
- * some medicines used to treat glaucoma
- * some medicines used to treat high blood pressure
- * corticosteroids such as prednisone and cortisone
- * glucagon, a medicine used to treat low blood glucose
- * some medicines used to treat tuberculosis
- * (high dose) nicotinic acid used for the lowering of blood fats
- * oestrogens and oral contraceptives
- * some medicines used to treat mental illness or psychotic disorders
- * phenytoin, a medicine used to treat epilepsy (convulsions)
- * cimetidine and ranitidine, medicines used to treat reflux and ulcers
- * ritodrine, a medicine used to prevent premature labour
- * diuretics, also known as fluid tablets
- * some asthma medicines, preparations for coughs and colds and weight-reducing medicines
- * thyroid hormones
- * large doses of laxatives
- * indomethacin, a medicine used to treat arthritis (an inflammatory condition)
- * barbiturates, medicines used for

sedation

Some medicines may hide the symptoms of low blood sugar (hypoglycaemia). These include:

- * alcohol
- * some medicines used to treat high blood pressure

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 Daonil.

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

How to take Daonil

Your doctor will decide what is the best dose for you and your condition.

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

They may differ from the information contained in this leaflet.

How much to take

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

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

When to take it

Take your tablet immediately before breakfast. If you only eat a very light breakfast then this dose should be put off until lunchtime. Swallow the tablets with a glass of water.

Do not skip meals whilst using Daonil. Take your dose at the

same times each day.

How long to take it

Continue taking Daonil for as long as your doctor recommends. Make sure that you have enough Daonil to last over weekends and holidays.

Daonil will help control your diabetes but will not cure it.

Therefore, you may have to take it for a long time. Currently there is no cure for diabetes.

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 soon as you remember, and then go back to taking your tablets as you would normally.

Missed doses can cause high blood sugar (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 that you missed.

If you double a dose this may cause low blood sugar (hypoglycaemia).

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Daonil. Do this even if there are no signs of discomfort or poisoning.

If you take too much Daonil you may experience symptoms of hypoglycaemia (low blood sugar).

If not treated quickly, these symptoms may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and

the occurrence of fits.

At the first signs of hypoglycaemia, raise your blood glucose quickly by taking jelly beans, sugar or honey, soft drink (non-diet) or glucose tablets.

If you experience any of the symptoms of an overdose, immediately get medical help.

While you are using Daonil

Things you must do

If you become pregnant while you are taking Daonil tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Daonil.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Daonil.

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

If you experience any of the symptoms of low blood sugar (hypoglycaemia), you need to raise your blood glucose urgently. You can do this by taking one of the following:

- * 5-7 jelly beans
- * 3 teaspoons of sugar or honey
- * 1/2 can of ordinary (non-diet) soft drink
- * 2-3 concentrated glucose tablets

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates eg. plain biscuits, fruit or milk - when over the initial symptoms. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

If you are elderly or are taking other medicines for diabetes such as

insulin or metformin, the risk of hypoglycaemia is increased.

The risk of hypoglycaemia is also increased in the following situations:

- * too much Daonil
- * too much or unexpected exercise
- * delayed meal or snack
- * too little food

If you experience any of the signs of high blood glucose (hyperglycaemia), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- * undiagnosed or uncontrolled diabetes
- * illness, infection or stress
- * too little Daonil
- * certain other medicines
- * too little exercise
- * eating more carbohydrate than normal

If you become ill or experience extra stress, injury, fever, infection or need surgery, tell your doctor.

Your blood glucose may become difficult to control at these times. Your doctor may decide to change your treatment and use insulin instead of Daonil.

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.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and your dietician's advice on diet, drinking alcohol and exercise.

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

Tell your doctor immediately if you notice the return of any symptoms you had before starting Daonil.

These may include lethargy or tiredness, headache, thirst, passing large amounts of urine and blurred vision.

These may be signs that Daonil is no longer working effectively, even though you may have been taking it successfully for some time.

Things you must not do

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

Do not skip meals while taking Daonil.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm.

Daonil may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn.

If outdoors, wear protective clothing and use a highly effective sunscreen. If you experience sunburn, tell your doctor immediately.

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, Daonil by itself is unlikely to affect how you drive or operate machinery.

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 eg, sugar sachets or jelly beans.
- * carry emergency food rations in case of a delay eg, dried fruit, biscuits or muesli bars
- * keep some Daonil readily available

If you become sick with a cold, fever or flu, it is very important to continue taking Daonil. If you have trouble eating solid food, use sugar-sweetened drinks as a carbohydrate substitute or 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

Check with your doctor as soon as possible if you have any problems while taking Daonil, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Daonil can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Daonil.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * signs of hypoglycaemia which may include weakness, trembling or shaking, sweating, light headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers
- * stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps
- * diarrhoea, constipation or a feeling of fullness in the stomach
- * loss of appetite
- * headache
- * weakness
- * eye problems including blurred or double vision

- * unusual weight gain

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- * convulsions or fits
- * deafness
- * blindness
- * severe pain or tenderness in the stomach
- * sudden onset of abnormal thoughts or delusions
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- * symptoms of lactic acidosis (too much acid in the blood) which may include loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, trouble breathing, feeling weak, tired or uncomfortable, unusual muscle pain, slow heart beat
- * rash, sores, redness or itching of the skin, itchy hives-like rash or spots
- * symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- * bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- * yellowing of the skin or eyes, also called jaundice
- * signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- * signs of anaemia such as tiredness, being short of breath and looking pale
- * a change in the colour or amount of urine passed, blood in the urine

In very rare cases, intolerance to alcohol may occur. Drinking large amounts of alcohol may interfere with the way Daonil works. It may not work at all or it may take much longer than usual to work.

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Daonil

Storage

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

If you take the tablets out the pack they may not keep as well.

Keep it in a cool dry place where the temperature stays below 25 degrees C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Daonil 5mg tablets are white, biplane oblong tablets with a score-line on both sides. LDI is engraved each side of the score-line and inverted. The other side is plain.

Ingredients

Active Ingredient:

- * 5mg glibenclamide per tablet

Inactive Ingredients:

- * lactose
- * maize starch
- * talc
- * colloidal silica
- * magnesium stearate

Daonil does not contain sucrose, tartrazine or any other azo dyes.

Sponsor

Daonil is supplied in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall No: 1800 818 806

Daonil is supplied in New Zealand by:
sanofi-aventis new zealand limited
Level 8, James and Wells Tower
Ellerslie, Auckland
New Zealand
Freecall No: 0800 283 684

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