

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Daonil?

Daonil contains the active ingredient glibenclamide. Daonil is used to control blood sugar levels in patients with type 2 diabetes mellitus. For more information, see Section [1. Why am I taking Daonil?](#) in the full CMI.

2. What should I know before I take Daonil?

Do not take if you have ever had an allergic reaction to glibenclamide, any other similar medicines (such as sulphur antibiotics or sulphonylureas), or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Do not give Daonil to children.

For more information, see Section [2. What should I know before I take Daonil?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Daonil and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Daonil?

- Your doctor will tell you how many tablets to take each day.
- Daonil should be swallowed with a full glass of water immediately before breakfast.
- More instructions can be found in Section [4. How do I take Daonil?](#) in the full CMI.

5. What should I know while taking Daonil?

Things you should do	• Remind any doctor, dentist, pharmacist or diabetes educator you visit 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. • Call your doctor straight away if you become pregnant or if you notice the return of any symptoms you had before starting Daonil.
Things you should not do	• Do not stop using this medicine suddenly. • Do not take Daonil to treat any other complaints unless your doctor tells you to. • Do not skip meals while taking Daonil.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Daonil affects you. • This medicine is not expected to affect your ability to drive a car or operate machinery.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store the tablets below 25°C. Protect from light. • Keep your tablets in the carton until it is time to take them.

For more information, see Section [5. What should I know while taking Daonil?](#) in the full CMI.

6. Are there any side effects?

Serious side effects may include sudden onset of abnormal thoughts, delusions, , rash, sores, redness, itching skin, itchy hives-like rash or spots, deafness, severe stomach pain or tenderness, sunburn symptoms, bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, jaundice, signs of frequent or worrying infections e.g. fever, severe chills, sore throat or mouth ulcers, anaemia signs e.g. tiredness, shortness of breath and looking pale; a change in colour or amount of urine passed, blood in the urine, lactic acidosis symptoms e.g. loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, trouble breathing, feeling weak, tired or uncomfortable, unusual muscle pain, slow heartbeat. Very serious side effects may include blindness, swelling of the face, lips or tongue which may cause difficulty in breathing, convulsions, fits.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Daonil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Daonil.**

Where to find information in this leaflet:

1. [Why am I taking Daonil?](#)
2. [What should I know before I take Daonil?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Daonil?](#)
5. [What should I know while taking Daonil?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking Daonil?

Daonil contains the active ingredient glibenclamide.

Daonil belongs to a group of medicines called sulphonylureas.

Daonil is used to control blood sugar levels in patients with type 2 diabetes mellitus.

This type of diabetes is also known as non-insulin-dependent diabetes (NIDDM) or adult-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.

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

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

Low blood sugar 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 sugar usually occurs more slowly than low blood sugar. Signs of high blood sugar may include:

- lethargy or tiredness
- headache
- severe thirst
- passing large amounts of urine and more often
- blurred vision
- dry mouth or dry skin.

Daonil is not addictive.

2. What should I know before I take Daonil?

Warnings

Do not take Daonil if:

- you are allergic to glibenclamide, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any other similar medicines (such as sulphur antibiotics or sulphonylureas).
- Always check the ingredients to make sure you can take this medicine.

Do not take Daonil if you:

- have type 1 diabetes mellitus (insulin-dependent diabetes mellitus, also known as IDDM, or juvenile-onset diabetes)
- have unstable diabetes
- have diabetic ketoacidosis
- have diabetic coma or pre-coma
- have severe kidney disease
- have severe liver disease
- are being treated with the medication bosentan.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have glucose-6-phosphate (G6PD) deficiency
- have a history of diabetic coma
- have adrenal, pituitary (or thyroid) problems
- have heart failure
- have kidney or liver problems
- drink alcohol in any amount
- do not eat regular meals
- do a lot of exercise or heavy work
- are feeling ill or unwell
- are taking any other antidiabetic treatment.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take Daonil if you are pregnant or planning to become pregnant.

Talk to your doctor if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

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

Do not take Daonil if you are breastfeeding or planning to breastfeed.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children

Do not give Daonil to children.

Safety and effectiveness in children has not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with Daonil and affect how it works.

Some medicines that may lead to low blood sugar (hypoglycaemia) by increasing the blood sugar lowering effect of Daonil include:

- 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
- pentoxifylline, 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 that may lead to high blood sugar (hyperglycaemia) by weakening the blood sugar lowering effect of Daonil include:

- 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 sugar

- 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
- some preparations for coughs and colds
- some weight reducing medicines
- thyroid hormones
- large doses of laxatives
- indometacin, a medicine used to treat arthritis (an inflammatory condition)
- barbiturates, medicines used for sedation.

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

- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Daonil.

4. How do I take Daonil?

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 sugar levels.
- Follow the instructions provided and take Daonil until your doctor tells you to stop.

This medicine helps to control your diabetes, but will not cure it. Therefore, you may have to take it for a long time. It is important to keep taking your medicine even if you feel well. Make sure you have enough Daonil to last over weekends and holidays.

When to take Daonil

- Daonil should be taken immediately before breakfast. If you only eat a very light breakfast, then this dose should be put off until lunchtime.

Do not skip meals whilst using Daonil.

Take your dose at the same time each day.

How to take Daonil

Swallow the tablets with a full glass of water.

If you forget to take Daonil

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 medicine as you would normally.

Missed doses can cause high blood sugar (hyperglycaemia).

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

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

If you are not sure what to do, ask your doctor, pharmacist or diabetes educator.

If you have trouble remembering to take your medicine, ask your doctor, pharmacist or diabetes educator for some hints.

If you take too much Daonil

If you think that you have taken too much Daonil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
- (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

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.

5. What should I know while taking Daonil?

Things you should do

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 sugar 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 e.g. plain biscuits, fruit or milk - when over the initial symptoms. Taking this extra carbohydrate will prevent a second drop in your blood sugar 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.

Tell your doctor if you:

- become ill
- experience extra stress
- are injured
- have a fever
- have a serious infection
- need surgery.

Your blood sugar 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 sugar 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 heartbeat, stomach pains or feel sick and vomit.

Call your doctor straight away if you:

- become pregnant
- 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.

- experience any of the signs of high blood sugar (hyperglycaemia).

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 carbohydrates than normal.

Remind any doctor, dentist, pharmacist, or diabetes educator you visit that you are taking Daonil.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Things you should not do

- Do not stop taking this medicine or lower the dosage without checking with your doctor.
- Do not take Daonil to treat any other complaints unless your doctor tells you to.
- Do not give your medicine 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 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.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Daonil affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

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

Low blood sugar 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may:

- lead to low blood sugar (hypoglycaemia) by increasing the blood sugar lowering effect of Daonil
- lead to high blood sugar (hyperglycaemia) by weakening the blood sugar lowering effect of Daonil
- hide the symptoms of low blood sugar.

Looking after your medicine

- Store the tablets below 25°C. Protect from light.
- Keep your tablets in the carton until it is time to take them.

If you take the tablets out of the carton they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date printed on the carton or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
Stomach and gut-related: • stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion, cramps • diarrhoea, constipation or a feeling of fullness in the stomach • loss of appetite. Alertness and sleep-related: • headache • weakness. Sight-related:	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- eye problems including blurred or double vision. Other: - 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 - unusual weight gain.	

Serious side effects

Serious side effects	What to do
Alertness and sleep-related: - sudden onset of abnormal thoughts or delusions. Allergy-related: - rash, sores, redness or itching of the skin, itchy hives-like rash or spots. Sight, hearing, smell, taste or touch-related: - deafness. Stomach and gut-related: - severe pain or tenderness in the stomach. Skin and muscle-related: - 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. Infection-related: - signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers. Other: - signs of anaemia such as tiredness, being short of breath and looking pale - a change in colour or amount of urine passed, blood in the urine. - symptoms of lactic acidosis (too much acid in the blood) which	Call your doctor as soon as possible if you notice any of these serious side effects.

Serious side effects	What to do
may include loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, trouble breathing, feeling weak, tired or uncomfortable, unusual muscle pain, slow heartbeat.	

Very serious side effects

Serious side effects	What to do
Alertness and sleep-related: - convulsions or fits. Allergy-related: - swelling of the face, lips or tongue which may cause difficulty in breathing. Sight, hearing, smell, taste or touch-related: - blindness.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at

<https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Daonil contains

Active ingredient (main ingredient)	glibenclamide 5 mg
Other ingredients (inactive ingredients)	- lactose monohydrate - maize starch - pre-gelatinised maize starch - purified talc - colloidal anhydrous silica - magnesium stearate.
Potential allergens	- lactose - sugars

	This medicine does not contain sucrose, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What Daonil looks like

Daonil 5 mg 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 (Aust R 73683).

Who distributes Daonil

Distributed in Australia by:
sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:
Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
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