

# DAPSOMED

## 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 using DAPSOMED?

DAPSOMED tablet contains Dapsone as the active ingredient. Dapsone (DAP-sone), a sulfone, belongs to the family of medicines called anti-infectives and is used to treat leprosy (Hansen's disease) and to help control a skin problem called dermatitis and a fungal disease called *Actinomycotic mycetoma*.

For more information, see Section [1. Why am I using DAPSOMED?](#) in the full CMI.

### 2. What should I know before I use DAPSOMED?

Do not use if you have ever had an allergic reaction to DAPSOMED or any other sulpha drugs 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.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with DAPSOMED 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 use DAPSOMED?

- Tablets should be taken whole and small doses should be made up from 50 mg tablets. Do not split the tablet.
- For best effect DAPSOMED must be taken regularly.

More instructions can be found in Section [4. How do I use DAPSOMED?](#) in the full CMI.

### 5. What should I know while using DAPSOMED?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell all the doctors, dentists and pharmacists who are treating you that you are taking Dapsone.</li><li>• Tell your doctor if the symptoms of your infection do not improve within 2 to 3 months, or if they become worse.</li><li>• If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Dapsone.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give Dapsone to anyone else, even if they have the same condition as you.</li><li>• Do not use Dapsone to treat any other complaints unless your doctor tells you to.</li><li>• If you do not complete the full course prescribed by your doctor, all of the bacteria/fungi causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Dapsone may make you dizzy. Be careful when driving a car or using machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C in a dry place.</li></ul>

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

### 6. Are there any side effects?

Like other medicines, Dapsone can cause some side effects. Common side effects could be: Severe skin rash, Muscle weakness, unusual tiredness or weakness, Yellowing of skin or eyes, Nausea, vomiting; Loss of appetite etc.

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.

# DAPSOMED

Active ingredient(s): *Dapsone*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DAPSOMED. **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 DAPSOMED.**

Where to find information in this leaflet:

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

### 1. Why am I using DAPSOMED?

**DAPSOMED contains Dapsone as the active ingredient.** Dapsone (DAP-son), a sulfone, belongs to the family of medicines called anti-infectives. Dapsone works by killing the bacteria or fungi causing your infection or by stopping its growth.

Dapsone will not work against infections caused by viruses such as colds or the flu.

Dapsone is used to treat leprosy (Hansen's disease) and to help control a skin problem called dermatitis and a fungal disease called *Actinomycotic mycetoma*. When it is used to treat leprosy, Dapsone may be given with one or more other medicines.

**Ask your doctor if you want any more information about this medicine.**

There is no evidence that DAPSOMED is addictive.

### 2. What should I know before I use DAPSOMED?

#### Warnings

**Do not use DAPSOMED if:**

- you have ever had an allergic reaction to Dapsone or any other sulpha drugs or any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include skin rash, which is always present, fever, jaundice, and eosinophilia.

**Check with your doctor if:**

- You have any type of allergic reaction to sulpha drugs (sulfonamide medicines):** You may have an increased chance of being allergic to Dapsone if you are allergic to sulpha drugs.
- You have allergies to:** any other medicines any other substances, such as foods, preservatives or dyes.
- you have or have had any medical conditions, including:** anemia, or liver or kidney disease
- the packaging is torn or shows signs of tampering.
- you are not sure whether you should start taking Dapsone.

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

**Check with your doctor if you are pregnant or intend to become pregnant.** The use of Dapsone during pregnancy should be avoided.

Dapsone may affect your developing baby if you take it during pregnancy.

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

Dapsone passes into breast milk and may affect your baby. Dapsone may cause blood problems in nursing babies. Therefore, breast feeding may need to be stopped because of the risks to the baby.

**If you have not told your doctor about any of the above, tell them before you are given DAPSOMED.**

### 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 DAPSOMED and affect how it works. These include:**

- Amprenavir
- Didanosin
- Rifampicin
- Clofazimine
- Probenecid
- Trimethoprim
- Cimetidine
- Pyrimethamine

You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

When you are taking DAPSOMED, it is especially important that your healthcare professional knows if you are taking any of the above.

Talk to your doctor about the need for an additional method of contraception while taking Dapsone.

Some medicines may decrease the effectiveness of some birth control pills, although this has not been shown with Dapsone.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Dapsone.

## 4. How do I use DAPSOMED?

### How much to take

- Keep taking your DAPSOMED for as long as your doctor tells you to. Remember it may take a number of months for Dapsone to work.
- Do not stop taking DAPSOMED even if you begin to feel better. For best effect DAPSOMED must be taken regularly.
- Do not take a double dose to make up for the dose that you missed.
- If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

### How to take DAPSOMED

- Take DAPSOMED with a full glass of water or another liquid, with or after food.
- The tablet can be divided into equal doses.
- Tablets should be taken whole and small doses should be made up from 50 mg tablets which can be divided evenly.

### If you use too much

If you think that you have used too much DAPSOMED, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**) or **0800 POISON** or **0800 764 766** (in New Zealand) for advice, 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.**

## 5. What should I know while using DAPSOMED?

### Things you should do

Tell your doctor:

- If the symptoms of your infection do not improve within 2 to 3 months, or if they become worse.
- If you become pregnant while you are taking Dapsone
- If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking Dapsone.

Your doctor may give you a schedule for regular blood tests. This schedule should be carefully followed—

- If you have to test your urine for sugar while you are using/being given Dapsone, make sure your doctor knows which type of test you use.
- Dapsone may affect the results of some of these tests.
- If you have to have any blood tests tell your doctor you are taking/using/ Dapsone.
- Dapsone may affect the results of some blood tests.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking Dapsone.

### Things you should not do

- Do not stop taking your tablets because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all of the bacteria/fungi causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.
- Do not give Dapsone to anyone else, even if they have the same condition as you.
- Do not use Dapsone to treat any other complaints unless your doctor tells you to.

### Driving or using machines

Dapsone may make you dizzy.

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

### Looking after your medicine

- Store below 25°C.
- 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.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

## 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.

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

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

### Less serious side effects

Side effects	What to do
<ul style="list-style-type: none"><li>• Nausea, vomiting;</li><li>• Loss of appetite</li><li>• stomach upsets</li><li>• headache</li><li>• nervousness</li><li>• dizziness</li></ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

### Very Serious side effects

Very Serious side effects	What to do
<ul style="list-style-type: none"><li>• Severe skin rash</li><li>• Muscle weakness, unusual tiredness or weakness</li><li>• Yellowing of skin or eyes</li><li>• Bluish finger nails, lips or skin</li><li>• Fever, sore throat and difficulty in breathing</li><li>• Back, leg or stomach pains</li><li>• Itching, dryness, redness, scaling or peeling of the skin</li><li>• Loss of hair</li><li>• Mood or other mental changes</li><li>• Numbness, tingling, pain, burning or weakness in hands or feet;</li><li>• Unusual bleeding or bruising</li></ul>	<b>Stop taking Dapsone and Call your doctor straight away, go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b>

**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.

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

### 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](http://www.tga.gov.au/reporting-problems) (in Australia) or <https://pophealth.my.site.com/carmreportnz/s/> (in New Zealand). 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 DAPSOMED contains

<b>Active ingredient (main ingredient)</b>	Dapsone
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• sodium lauryl sulfate</li><li>• maize starch</li><li>• colloidal anhydrous silica</li><li>• magnesium stearate</li></ul>
<b>Potential allergens</b>	None

**Do not take this medicine if you are allergic to any of these ingredients.**

### What DAPSOMED looks like

DAPSOMED 50mg tablets are white or slight yellowish, round, biconvex tablets, debossed with "50" on one side, with a score line on the other side - AUST R 403657

DAPSOMED 100mg tablets are white or slight yellowish, round, biconvex tablets, debossed with "D" on one side, with a score line on the other side - AUST R 403659

Available as Alu-PVC blister packs of 100 tablets.

### Who distributes DAPSOMED

Medsurge Pharma Pty Ltd

Unit 1& 2, 6-7 Gilda Court

Mulgrave, Victoria 3170

Marketed and Distributed in Australia & New Zealand by Medsurge Healthcare.

Telephone (AU): 1300 788 261

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