DAPSONE

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 Dapsone?

Dapsone contains the active ingredient dapsone. Dapsone is used to treat leprosy (Hansen's disease) and to help control a skin problem called dermatitis herpetiformis, and a fungal disease called Actinomycotic mycetoma.

For more information, see Section 1. Why am I taking Dapsone? in the full CMI.

2. What should I know before I take Dapsone?

Do not take if you have ever had an allergic reaction to Dapsone or any other sulfone drugs or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have or have had any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding or intend to breast feed.

For more information, see Section 2. What should I know before I take Dapsone? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dapsone 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 Dapsone?

- Take Dapsone with a full glass of water or another liquid, with or after food
- Tablets should be swallowed whole. Do not split the tablet

More instructions can be found in Section 4. How do I take Dapsone? in the full CMI.

5. What should I know while taking Dapsone?

Things you must do	 Remind any doctor, dentist or pharmacist you visit that you are using Dapsone If the symptoms of your infection do not improve within 2 to 3 months, or if they become worse, tell your doctor If you become pregnant while you are taking Dapsone tell your doctor immediately 	
Things you must not do	Do not stop taking your tablets because you are feeling better, unless advised by your doctor	
Driving or using machines		
Looking after your medicine	Store the pack in a cool dry place below 25°C, protected from light, where children cannot reach it	

For more information, see Section 5. What should I know while taking Dapsone? in the full CMI.

6. Are there any side effects?

If any of the following happen, stop taking Dapsone and tell your doctor immediately. You may need urgent medical attention. Signs of an allergic reaction such as severe skin rash, yellowing of skin or eyes, fever, difficulty breathing. Numbness. Tingling. Weakness in hands or feet. Muscle weakness. Unusually severe tiredness or weakness. Bluish fingernails, lips or skin. Itching, dryness, redness, scaling or peeling of the skin. Severe fatigue, joint pain and loss of hair. Mood or other mental state changes. Chest pain, wheezing, shortness of breath. Swelling around the eyes, ankles, and feet. Pain and tenderness with impaired sensation and/or hypersensitivity in the testicles, eyes, or joints. Loss of sensation or movement in the hands and feet.

Tell your doctor if you notice any of the following and they worry you: Nausea. Vomiting. Loss of appetite. Headache. Nervousness. Dizziness. Difficulty sleeping. Stomach pain. Back pain. Loss of hair. Blurred vision. Ringing in the ears (tinnitus). Rapid heartbeat. Increased skin sensitivity to sunlight. Swelling of existing leprosy skin and nerve lesions.

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.

DAPSONE

Active ingredient: dapsone

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dapsone. 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 Dapsone.

Where to find information in this leaflet:

- 1. Why am I taking Dapsone?
- 2. What should I know before I take Dapsone?
- 3. What if I am taking other medicines?
- 4. How do I take Dapsone?
- 5. What should I know while taking Dapsone?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Dapsone?

Dapsone contains the active ingredient dapsone.

Dapsone, 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 herpetiformis and a fungal disease called Actinomycotic mycetoma. When it is used to treat leprosy, Dapsone may be given with one or more other medicines.

2. What should I know before I take Dapsone?

Warnings

Do not use Dapsone if:

- You have ever had an allergic reaction to Dapsone, to sulfones, or to any of the ingredients listed at the end of this leaflet
- Always check the ingredients to make sure you can use this medicine

Tell your doctor if you:

- Have any type of allergic reaction to sulfone drugs.
- Take any medicines for any other condition
- Have any allergies to any other medicines any other substances, such as foods, preservatives or dyes
- Have or have had any medical conditions, including: porphyria, anemia, or heart, lung, liver or kidney disease

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 <u>6</u>. <u>Are there any side effects?</u>

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. Don't use Dapsone while pregnant unless advised by your doctor.

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

Tell your doctor if you are breastfeeding or intend to breastfeed. Dapsone passes into breast milk and may cause blood problems in nursing babies. Therefore, breast feeding may need to be stopped because of the risks to the baby.

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 be affected by Dapsone or affect how it works. These include:

- Medicines for the treatment of HIV (amprenavir, didanosine)
- Some antibiotics (rifampicin, trimethoprim
- Some medicines for the treatment of leprosy (clofazimine)
- Medicine for the treatment of gout (probenecid)
- Medicine for the treatment of stomach or intestinal ulcers (cimetidine)
- Some antimalarials (pyrimethamine, chloroquine, primaquine)

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

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

4. How do I take Dapsone?

How much to take / use

Dermatitis herpetiformis: The usual dosage is 50 to 100 mg daily, but as little as 50 mg weekly may be adequate.

Leprosy: When used for leprosy, Dapsone is usually taken with one or more other drugs to prevent the development of resistance.

The usual dose in adults is 100 mg. Dapsone dosing in children is based on the child's body weight.

Actinomycotic Mycetoma: The usual adult dose is 100 mg taken twice a day.

Take Dapsone with a full glass of water or another liquid, with or after food.

Tablets should be swallowed whole. Do not split the tablet.

Keep taking your Dapsone 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 Dapsone even if you begin to feel better, unless directed by your doctor.

If you forget to take Dapsone

Dapsone must be taken regularly.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you take too much Dapsone

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

You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26 (in Australia) 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 taking Dapsone?

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 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. This may include testing your urine for sugar and/or blood tests.

Tell your doctor immediately if:

• You become pregnant while you are taking Dapsone

Remind any doctors, dentists or pharmacists you visit 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

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

Dapsone may cause dizziness in some people

Looking after your medicine

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

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 windowsills

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking Dapsone, 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 be serious and 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.

Less serious side effects

Less serious side effects	What to do
Gut and digestion: Nausea Vomiting Loss of appetite Other: Headache Neryousness	Speak to your doctor if you have any of these less serious side effects and they worry you.

•	Dizziness	Speak to your
•	Difficulty sleeping	doctor if you
•	Stomach pain	have any of
•	Back pain	these less
•	Loss of hair	serious side
•	Blurred vision	effects and
•	Ringing in the ears (tinnitus)	they worry you.
•	Rapid heartbeat	
•	Increased skin sensitivity to	
	sunlight	
•	Swelling of existing leprosy skin	
	and nerve lesions	

Serious side effects

These are very serious side effects.

Serious side effects	What to do
Signs of an allergic reaction such as: Severe skin rash Yellowing of skin or eyes Fever Difficulty breathing Nervous system: Numbness Tingling Weakness in hands or feet Whole body: Muscle weakness Unusually severe tiredness or weakness Bluish fingernails, lips or skin Itching, dryness, redness, scaling or peeling of the skin Severe fatigue, joint pain and loss of hair Mood or other mental state changes Chest pain, wheezing, shortness of breath Swelling around the eyes, ankles, and feet Pain and tenderness with impaired sensation and/or hypersensitivity in the testicles, eyes, or joints Loss of sensation or movement in the hands and feet	Stop taking Dapsone and 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 https://nzphvc.otago.ac.nz/consumer-reporting/ (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 Dapsone contains

Active ingredient	dapsone
(main ingredient)	
Other ingredients	starch-maize
(inactive ingredients)	cellulose-microcrystalline
	magnesium stearate
	silicon dioxide

Tablets do not contain alcohol, gluten, lactose, parabens, sugar, sulfite or tartrazine.

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

What Dapsone looks like

Tablets (white, scored): 100's 25 mg tablets (AUST R 104482) 100 mg tablets (AUST R 104483)

Who distributes Dapsone

Manufactured by:

Jacobus Pharmaceutical Co. Inc. (USA)

Supplied and distributed in Australia by:

Link Medical Products Pty Ltd

5 Apollo Street

Warriewood, NSW 2102, Australia

Ph: 1800 181 060

linkhealthcare.com.au

Supplied and distributed in NZ by:

Link Pharmaceuticals Ltd

Suite 38, Level 8

139 Quay Street

Auckland 1010

New Zealand

Ph: +64 (9) 358 7146

This leaflet was prepared in April 2024.