

DAPSONE TABLETS CONSUMER MEDICINE INFORMATION LEAFLET

WHAT IS IN THIS LEAFLET?

This leaflet answers some common questions about Dapsone. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT DAPSONE IS USED FOR?

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

Mechanism of action:

DAPSONE (DAP-sone), 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 available only with a doctor's prescription.

There is no evidence that Dapsone is addictive.

BEFORE TAKING DAPSONE

When you must not take it?

When you must not be given it?

Do not take/use Dapsone 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.

Tampering and Expiry Date Warnings:

Do not use Dapsone if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking DAPSONE, contact your doctor.

Before you start to take it

Before you are given it

Tell your doctor if:

1. ***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.

2. ***you have any allergies to:***
any other medicines any other substances, such as foods, preservatives or dyes.
3. ***Pregnancy and breast-feeding:*** 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.
4. ***you are breast-feeding or intend to breast-feed.***
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.
5. ***if you have or have had any medical conditions, including:***
anemia, or liver or kidney disease

If you have not told your doctor about any of the above, tell them before you take/are given DAPSONE.

TAKING OTHER MEDICINES

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy (over-the-counter products), supermarket or health food shop.

Some medicines may interfere with DAPSONE. These include:

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

These medicines may be affected by DAPSONE, or may affect how well it works. 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.

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.

HOW TO TAKE DAPSONE?

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

Tablets should be taken whole and small doses should be made up from 25 mg tablets. Do not split the tablet.

How long to take it?

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. For best effect Dapsone 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.

If you take too much (overdose)

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

WHILE YOU ARE USING DAPSONE

Things you must do

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.

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 must 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.¹²

Things to be careful of

Dapsone may make you dizzy. Be careful when driving a car or using machinery.

SIDE EFFECTS

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.

Like other medicines, Dapsone 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.

While taking DAPSONE

If any of the following happen, stop taking Dapsone and tell your doctor immediately. These are very serious side effects. You may need urgent medical attention or hospitalisation

- Severe skin rash
- Muscle weakness, unusual tiredness or weekness
- Yellowing of skin or eyes
- Bluish finger nails, lips or skin
- Fever, sore throat and difficulty in breathing
- Back, leg or stomach pains
- Itching, dryness, redness, scaling or peeling of the skin
- Loss of hair
- Mood or other mental changes
- Numbness, tingling, pain, burning or weekness in hands or feet;
- Unusual bleeding or bruising

Tell your doctor if you notice any of the following and they worry you: These side effects are usually mild.

- Nausea, vomiting;
- Loss of appetite;
- Headache;
- Nervousness - Dizziness

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Some people may get other side effects while taking/using/being given DAPSONE.

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

STORAGE

Keep your tablets in the original pack until it is time to take them. Keep the pack in a cool dry place. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Store all medicines out of the reach of children such as in a locked cupboard.

If your doctor tells you to stop taking DAPSONE, ask your pharmacist what to do with any tablets that are left over.

Store below 25°C. Protect from light.

WHAT IT LOOKS LIKE?

Tablets, 25mg and 100mg (white, scored): 100's

Ingredients

Active. Dapsone.

Inactive. Starch-maize, cellulose-microcrystalline, magnesium stearate, silicon dioxide

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

Manufacturer / Distributor / Supplier

Link Medical Products Pty Ltd
Level 1, 3 Brady Street
Mosman NSW 2088, Australia
Ph (02) 9960 0150

AUST R 104482, 25 mg Dapsone
AUST R 104483, 100 mg Dapsone

Prepared on 31 May 2004
Revised on 18 November 2004