

Package leaflet: Information for the user

Dapsone 25mg, 50mg and 100mg Tablets

dapsone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dapsone tablets are and what they are used for
2. What you need to know before you take Dapsone tablets
3. How to take Dapsone tablets
4. Possible side effects
5. How to store Dapsone tablets
6. Contents of the pack and other information

1. What Dapsone tablets are and what they are used for

Dapsone tablets contain the active substance dapsone, which belongs to a group of medicines called antibacterials. It works by stopping the production of folic acid in certain bacteria, therefore stopping them growing.

Dapsone tablets may be used for:

- Leprosy
- Skin problems
- Prevention of malaria in combination with pyrimethamine
- Prevention of pneumonia in immunodeficient patients, especially in AIDS patients.

2. What you need to know before you take Dapsone tablets

Do not take Dapsone tablets :

- if you are **allergic** (hypersensitive) to dapsone, any of the other ingredients in the tablet, or to similar medicines such as sulfonamide or sulfone (see section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you suffer from **severe anaemia**
- if you have **porphyria** (a genetic or inherited disorder of the red blood pigment, haemoglobin)
- if you suffer from **severe** glucose-6-phosphate dehydrogenase deficiency (**G6PD**), this can cause episodes of anaemia after eating certain foods such as fava beans (favism).

Tell your doctor if you have any of the above

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dapsone tablets:

- if you suffer from other **blood disorders**
- if you suffer from **heart** or **lung** disease.

Other medicines and Dapsone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- **Probenecid** (to treat gout)
- **Rifampicin** or **trimethoprim** (antibiotic to treat infections).

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor may prescribe you folic acid supplements.

Dapsone can be present in breast milk. There has been a report of anaemia in an infant being breast fed by a mother taking Dapsone tablets.

If you are concerned, check with your doctor or pharmacist.

Dapsone tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Dapsone tablets

Always take Dapsone tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **with some water**.

The recommended doses are:

- **Adults and children over 12 years:**

Multibacillary leprosy: 100mg daily for at least two years.

Paucibacillary leprosy: 100mg daily for at least six months.

Malaria prophylaxis: 100mg weekly with 12.5mg pyrimethamine.

Dermatitis herpetiformis: Initially 50mg daily which may be gradually increased to 300mg daily and then reduced to a usual maintenance dose of 25mg-50mg daily.

Pneumocystis carinii pneumonia: In combination with trimethoprim, 50-100mg daily or 100mg twice weekly or 200mg once weekly.

- **Elderly:**

If you have a damaged liver your doctor may give you a lower dose.

- **Children 6-12 years:**

Multibacillary leprosy: 50mg daily for at least two years.

Paucibacillary leprosy: 50mg daily for at least six months.

Continue to take them for as long as your doctor tells you to, it may be dangerous to stop without their advice.



Dapsone 25mg, 50mg
and 100mg tablets

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If you take more Dapsone tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include slow heart rate, bluish skin, feeling tired or weak, pale skin, headache, dizziness, confusion, fever, jaundice.

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Dapsone tablets

Do not stop taking Dapsone tablets without your doctor's advice as it may be dangerous.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, particularly when you first start taking it, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Contact your doctor or go to the nearest hospital immediately if you notice any of the following serious side effect:

- **Dapsone syndrome:** a 'dapsone syndrome' may occur after 3-6 weeks of treatment. Symptoms always include rash, fever and changes in blood cells. It is important to seek medical help immediately as severe skin reactions, inflammation of the liver, kidney damage and mental illness have occurred if treatment is not stopped or reduced. Some deaths have been reported.
- **Effects on your leprosy:** if you are being treated for leprosy and your condition does not improve or you get eye or nerve damage, talk to your doctor.

Tell your doctor if you notice any of the following side effects or you notice any other effects not listed:

- **Effects on the blood:** anaemia caused by destruction of red blood cells, changes in the type and number of other blood cells (you may develop ulcers in your mouth or on your skin).
- **Effects on the skin:** rash which can be raised, discoloured, tender, destructive or itchy, sensitivity to sunlight or artificial light such as sunbed (symptoms such as tingling, burning or redness of the skin). Rarely skin conditions may be associated with fever, malaise, lung or kidney damage.
- **Effects on the nervous system:** headache, difficulty sleeping, nerve damage which may cause tingling in your arms or legs and some weakness.
- **Effects on the gastrointestinal system:** loss of appetite, feeling or being sick, inflammation of the liver.
- **Other effects:** fast heart beat, mental disturbances, changes in liver function tests, jaundice.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dapsone tablets

Keep this medicine out of the sight and reach of children.

Do not use Dapsone tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dapsone tablet contains

- The active substance (the ingredient that makes the tablet work) is Dapsone. Each tablet contains 25 mg, 50mg or 100mg of the active ingredient.
- The other ingredients are lactose monohydrate, maize starch, silica colloidal anhydrous, water purified, sodium lauryl sulfate, magnesium stearate.

What Dapsone tablets look like and contents of the pack

Dapsone tablets 25mg are white to off-white, capsule shape, biconvex, uncoated tablets debossed with "J 16" on one side and plain on other side.

Dapsone tablets 50mg are white to off white, circular, biconvex, uncoated tablets debossed with "J" and "5" separated by break line on one side and plain on other side.

Dapsone tablets 100mg are white to off white, circular, biconvex, uncoated tablets debossed with "J" and "6" separated by break line on one side and plain on other side.

Dapsone 25mg, 50mg and 100mg tablets are available in cold form laminate blisters with aluminium foil packs.

Pack size 28

MACLEODS


Marketing Authorisation Holder and Manufacturer

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