

Package Leaflet: Information for the user

Dapsone 50 mg and 100 mg 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dapsone Tablets is and what it is used for
2. What you need to know before you take Dapsone Tablets
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1. What Dapsone Tablets is and what it is used for

Dapsone 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 may be used for:

- Leprosy
- skin problems
- the prevention of malaria in combination with pyrimethamine
- the 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 and tell your doctor 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
- suffer from severe anaemia
- have porphyria (a genetic or inherited disorder of the red blood pigment, haemoglobin)
- suffer from severe glucose-6-phosphate dehydrogenase deficiency (G6PD), this can cause episodes of anaemia after eating certain foods such as fava beans (favism).

Take special care with Dapsone tablets and **tell** your doctor if you:

- suffer from other blood disorders
- suffer from heart or lung disease.

Taking other medicines

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

- probenecid (to treat gout)
- rifampicin or trimethoprim (antibiotics to treat infections).

Ask your doctor or pharmacist for advice before taking any medicines.

Pregnancy and breastfeeding

If you are pregnant or planning to become pregnant, 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.

Ask your doctor or pharmacist for advice before taking any medicines.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3. How to take Dapsone Tablets

Always take Dapsone tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist. Swallow the tablets with some water.

The usual 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.

Fonts used

Helvetica Neue 57 Condensed - Text with 8 Pts.

Helvetica Neue 77 Bold Condensed - Heading with 14 Pts.

Helvetica Neue 57 Condensed - API with 10 Pts.

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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.

If you take more 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.

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.

4. Possible side effects

Like all medicines, Dapsone tablets 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 at once if the following occur:

- **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 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 sun-bed (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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dapsone Tablets

Keep out of the reach and sight of children.

Store at 20°C - 25°C .

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. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Dapsone tablets contain

The active substance is Dapsone.

Each tablet contains either 50mg or 100mg of the active ingredient.

The other ingredients are Microcrystalline Cellulose PH 102, Sodium Lauryl sulphate, Croscarmellose Sodium, Polyvinyl Pyrolidone K-30, Magnesium Stearate & Purified water.

What Dapsone tablets look like and contents of the pack

Dapsone 50mg Tablets:

White to off white colored, circular shaped, biconvex uncoated tablet impressed with "C" on one face and "DP" on either side of a central division line on the other face.

Dapsone 100mg Tablets:

White to off white colored, circular shaped, biconvex uncoated tablet impressed with "C" on one face and "DS" on either side of a central division line on the other face.

Pack size: 10's

Marketing Authorisation Holder

Somex Pharma
Ilford, Essex, IG3 8BS.UK

Manufacturer

Somex Pharma
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