

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 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, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dapsone 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.

Your doctor will explain what you are being treated for; if not you should ask the doctor.

2. What you need to know before you take Dapsone

Do not take Dapsone tablets and tell your doctor if you:

- are allergic (hypersensitive) to dapsone or any of the other ingredients (listed in section 6) in the tablet.
- are allergic 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 lack of iron in your blood (severe anaemia).
- have a genetic or inherited disorder of the red blood pigment, haemoglobin, called porphyria.
- suffer from severe glucose-6-phosphate dehydrogenase deficiency (G6PD), this can cause episodes of anaemia after eating certain foods such as fava beans (favism). People of African, Asian, or Mediterranean ancestry are especially at risk of this.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dapsone:

- if you suffer from any other blood disorder.
- if you have heart disease.
- if you have lung disease.

Other medicines and Dapsone

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

It is especially important:

- if you are taking a medicine for gout called probenecid.
- if you are taking antibiotics for infections called rifampicin, rifabutin, or trimethoprim.
- if you are to have an oral typhoid vaccination, as it may not be effective.

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

Dapsone with food and drink

You can take dapsone before, during, or after meals, including with milk.

Pregnancy, breast-feeding and fertility

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.

You may be prescribed folic acid supplements by your doctor if you are pregnant or planning to become pregnant.

Dapsone can be present in breast milk. There have been reports of low iron in blood (anaemia) of infants breast-fed while the mother has been taking Dapsone. If you are breast-feeding, or you are concerned, you should discuss this with your doctor.

Dapsone may reduce the number and/or the movement of sperm; this may make it more difficult to make your partner pregnant; if you are concerned you should discuss this with your doctor or pharmacist.

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

Driving and using machines

Dapsone should not affect your ability to drive or operate machinery.

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

Always take this medicine 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.

Use in Adults and Children over 12 years:

Multibacillary(also called MB or lepromatous) leprosy:100mg daily for at least two years.

Paucibacillary(also called PB or tuberculoid) leprosy:100mg daily for at least six months.

Malaria prophylaxis or Prevention of Malaria:100mg weekly with 12.5mg pyrimethamine.

Dermatitis herpetiformis or Intensely itchy, blistering rash, called 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 or Pneumonia caused by a germ called Pneumocystis carinii: in combination with another medicine called trimethoprim: In combination with trimethoprim, 50-100mg daily or 100mg twice weekly or 200mg once weekly.

Use in the Elderly

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

Use in Children 6-12 years:

Multibacillary (also called MB or lepromatous) leprosy: 50mg daily for at least two years.

Paucibacillary(also called PB or tuberculoid) 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 Dapsone than you should

If you, or someone else swallow a lot of tablets together, or you think a child may have swallowed some, contact your nearest hospital emergency department, or tell your doctor immediately.

If you forget to take Dapsone

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

You should continue to take Dapsone for as long as you doctor tells you to do so. It may be dangerous to stop taking Dapsone without your doctor telling you to stop.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately if the following occur:

- **Dapsone syndrome:** Rarely (may affect up to 1 in 1,000 people) a condition called “dapsone syndrome” may occur after 3 - 6 weeks of treatment. The signs always include rash, high temperature, and changes in blood cells. You must seek medical advice at once since severe skin reactions, liver inflammation, 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 the condition does not improve or if you get eye damage or nerve damage, you should talk to your doctor at once.

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

Common (may affect up to 1 in 10 people):

- Haemolysis (destruction of red blood cells), which may make you feel tired.
- Shortness of breath, feeling tired, bluish tinge to the skin (Methaemoglobinaemia).

Uncommon (may affect up to 1 in 100 people):

- Lack of iron in the blood (anaemia), caused by destruction of red blood cells, which may make you feel tired.
- Fast heart-beat.
- Loss of appetite.
- Nausea.
- Vomiting.
- Inflammation of the liver characterised by tiredness, abdominal pain, poor appetite (hepatitis).
- Yellowing of skin or whites of the eye (jaundice).
- Changes in liver function tests (your doctor will check this).
- Low levels of albumin in the blood (Hypoalbuminaemia) - your doctor will check this.

- Headache.
- Nerve damage which may result in tingling in your arms or legs and some weakness (peripheral neuropathy, peripheral motor neuropathy).
- Difficulty in sleeping.
- Hallucinations, delusions, excessive movements, loss of contact with reality (Psychosis).
- Skin being more sensitive to the sun or to light (photosensitivity).
- Itching.
- Skin rash.

Rare (may affect up to 1 in 1,000 people):

- Sudden fever, chills, soreness of the throat, mouth and gums, mouth ulcers, gum bleeding (Agranulocytosis).
- A serious skin reaction with symptoms such as rash, blistering or peeling of the skin (Exfoliative dermatitis).
- Severe, raised, red, lumpy rash (Maculopapular rash).
- Red, painful raised rash, with skin loss (Toxic epidermal necrolysis).
- Flu like symptoms, followed by a red or purple rash which spreads and forms blisters, followed by skin loss (Stevens-Johnson syndrome).

Very rare (may affect up to 1 in 10,000 people):

- Well defined, round or oval areas of reddening and swelling of the skin, typically on the arms and legs (Fixed drug eruptions).

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

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What Dapsone contains

- The active substance (the ingredient that makes the tablets work) is Dapsone. Each tablet contains either 50mg or 100mg of the active ingredient.
- The other ingredients (excipients) are Lactose monohydrate; Maize starch; Sodium laurilsulfate (E487); Colloidal anhydrous silica (E 551); Magnesium stearate (E 470b).

What Dapsone looks like and contents of the pack

Dapsone tablets are white or slightly yellowish, round, biconvex tablets, debossed with “D” on one side and with a score line on the other side.

Pack sizes is 28 tablets

Marketing Authorisation Holder and Manufacturer

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