



Package leaflet: Information for the user

Dapsone

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

Dapsone belongs to a group of medicines called antibacterials. It works by stopping the production of folic acid in certain bacteria, therefore preventing them from growing.

Dapsone can be used to:

- treat leprosy
- treat blistering skin disorders such as dermatitis herpetiformis (which is connected to gluten sensitivity)
- prevent pneumonia in immunodeficient patients (in particular patients with AIDS).

2. What you need to know before you take Dapsone

Do not take Dapsone tablets:

- if you are **allergic** (hypersensitive) to dapsone, any of the other ingredients of this medicine, or to similar medicines such as sulfonamide or sulfone (see section 6). An allergic reaction may include 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).
- if you have severe liver disease.

If any of the above applies to you, talk to your doctor, pharmacist or nurse.

Warnings and precautions

Talk to your doctor, pharmacist or nurse if you:

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

Children and adolescents

Since there is no data available for the use of Dapsone tablets in children aged less than 6 years, Dapsone tablets cannot be given in this age group.

For children aged 6-12 years and adults and adolescents over 12 years, please refer to section 3.

Other medicines and Dapsone tablets

Please tell your doctor, pharmacist or nurse if you are taking any of the below listed medicines or if have recently taken any other medicines, including medicines obtained without a prescription:

- probenecid (to treat gout)
- rifampicin or trimethoprim (antibiotics used to treat infections)
- oral typhoid vaccination;
- saquinavir (to treat AIDS or HIV-I infections).

Ask your doctor, pharmacist or nurse for advice before taking any medicines whilst being treated with Dapsone tablets.

Driving and using machines

Dapsone tablets has no effect on the ability to drive or operate machinery.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. Your doctor may prescribe you folic acid supplements. Dapsone can be present in breast milk. There have been reports of anaemia in infants being breast fed by mothers taking Dapsone tablets. If you are concerned, check with your doctor, pharmacist or nurse. Ask your doctor, pharmacist or nurse for advice before taking any medicines whilst breastfeeding.

3. How to take Dapsone tablets

Always take this medicine exactly as your doctor has told you. If you are not sure, check with your doctor, pharmacist or nurse if you are not sure.

Swallow the tablets with a glass of water. The tablet can be divided into equal doses.

The recommended doses are:

- **Adults and adolescent aged over 12 years**

Multibacillary leprosy:

100mg daily for at least 2 years.

Paucibacillary leprosy:

100mg daily for at least six months.

Dermatitis herpetiformis:

Initially 50mg daily which may be gradually increased to 300mg daily and then reduced back down to the usual maintenance dose of 25mg-50mg daily.

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

- **Elderly**

If you have liver problems, 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

- **Children aged less than 6 years:**

The safety and efficacy of Dapsone in children aged less than six years has not been established.

If you take more Dapsone tablets than you should

If you take more Dapsone tablets than you should, 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 Dapsone 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 talking to your doctor, pharmacist or nurse. Your medicine may not work properly if you stop taking it too soon.

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

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, pharmacist or nurse if you notice any of the following effects or any effects not listed in this leaflet.

Contact your doctor immediately if the following occur:

- **Dapsone syndrome:** a 'dapsone syndrome' may occur 3-6 weeks after treatment. Symptoms 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 immediately. Some deaths have been reported.
- **Effects on your leprosy:** if you are being treated for leprosy and your condition does not improve or if you experience any eye or nerve damage.

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

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 heartbeat
- 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 and 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 tablets

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

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

This medicinal product does not require any special storage conditions.

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 is dapsone. Each tablet contains either 50mg or 100mg of the active ingredient.
- The other ingredients are cellulose microcrystalline (Grade – 102), maize starch, silica colloidal anhydrous and magnesium stearate.

What Dapsone tablets look like and contents of the pack

Dapsone 50mg tablets are white to off-white, uncoated, circular, biconvex tablets debossed "50" above and "D" below the score on one side and plain on the other side.

Dapsone 100mg tablets are white to off-white, uncoated, circular, biconvex tablets debossed "100" above and "D" below the score on one side and plain on the other side.

Dapsone 50mg and 100mg tablets are available in white opaque PVC-Aluminium foil blister pack.

Blister pack sizes: 28 tablets

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This leaflet was last revised in 08/2020.