

PACKAGE LEAFLET

Package leaflet: Information for the patient

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 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 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
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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 preventing them from growing.

Dapsone can be used to treat leprosy, to treat blistering skin disorders such as dermatitis herpetiformis (which is connected to gluten sensitivity) or to prevent pneumonia in immunodeficient patients (in particular patients with AIDS).

2. What you need to know before you take Dapsone

Do not take Dapsone:

- if you are allergic to dapsone, sulfonamides, sulfones or any of the other ingredients of this medicine listed in section 6.
- if you suffer from severe anaemia;
- if you have porphyria (A group of rare inherited or acquired disorders where there is a problem with the production of haem (used to make haemoglobin in red blood cells) within the body);
- if you suffer from severe glucose-6-phosphate dehydrogenase deficiency (A hereditary condition in which red blood cells break down when the body is exposed to certain medicines or infection);

Warnings and Precautions

Talk to your doctor or pharmacist before taking Dapsone if you:

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

Other medicines and Dapsone

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

- probenecid (to treat gout);
- rifampicin or trimethoprim (to treat infections);

Driving and using machines

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

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are no or very limited data from the use of dapsone in pregnant women. The use of dapsone is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

Dapsone is excreted in breast milk. Effects on the breastfed newborn/infant cannot be excluded.

3. How to take Dapsone

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

Swallow the tablets whole with a glass of water.

The tablets can be divided into equal doses.

Unless otherwise prescribed by the doctor, the recommended doses are:

• Adults and children (aged over 12 years):

Multibacillary leprosy: 100mg daily for at least two 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 carinii pneumonia: In combination with trimethoprim, 50-100mg daily or 100mg twice weekly or 200mg once weekly.

• Children aged 6-12 years:

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

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

• Elderly:

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

If you take more Dapsone than you should

If you accidentally take more Dapsone than you should, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose are: (low level of oxygen in the blood (hypoxia), methaemoglobinaemia (blood disorder in which an abnormal amount of methemoglobin (a form of haemoglobin) is produced) and haemolytic anaemia (reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness).

If you forget to take Dapsone

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Dapsone

Do not stop taking Dapsone without first talking to your doctor. Your medicine may not work properly if you stop taking it too soon.

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

4. Possible side effects

Like all medicines, Dapsone can cause side effects, particularly when you first start taking it, although not everybody gets them.

Stop taking Dapsone and seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness.
- Severe blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis).
- "Dapsone syndrome". Fever, malaise, skin rashes, jaundice, swollen lymph glands, glandular fever, eosinophilia (increase in white blood cells), anaemia (low blood count) may occur.

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 (breakdown of red blood cells).
- A blood disorder in which an abnormal amount of methemoglobin (a form of haemoglobin) is produced (methaemoglobinaemia).

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

- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia).
- Faster heartbeat (tachycardia).
- Loss of appetite (anorexia).
- Feeling or being sick (nausea, vomiting).
- Inflammation of the liver (hepatitis).
- Yellowing of skin or whites of the eyes (jaundice).

- Changes in liver function tests.
- Low levels of albumin in the blood (hypoalbuminaemia).
- Headache.
- Nerve damage affecting movement processes (peripheral neuropathy, peripheral motor neuropathy).
- Difficulty in sleeping (insomnia).
- Mental illness (psychosis).
- Abnormal sensitivity of the skin to sunlight (photosensitivity).
- Severe itching (pruritis).
- Skin rash.

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

- Depletion of white blood cells (agranulocytosis).
- Peeling of the skin over large areas of the body (exfoliative dermatitis).

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

- A type of allergic reaction to a medicine causing skin lesions (fixed drug eruption).

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.

Do not use Dapsone after the expiry date which is stated on the label/carton. 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 protect the environment.

6. Contents of the pack and other information

What Dapsone contains

- The active substance is dapsone. Each tablet contains either 50mg or 100mg of dapsone.
- The other ingredients are maize starch, silica colloidal anhydrous, magnesium stearate and microcrystalline cellulose.

What Dapsone looks like and contents of the pack

Dapsone Tablets come in aluminium and PVC/PVDC Unit Dose blister packs.

Dapsone 50mg Tablets are available in packs of 28, 50 and 100 tablets.

Dapsone 100mg Tablets are available in packs of 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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¹ Only actual site will be listed on printed leaflet