

**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, 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 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 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 (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 in children aged less than 6 years, Dapsone 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**

Tell your doctor, pharmacist or nurse 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 (antibiotics 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.

### **Driving and using machines**

Dapsone has no 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, 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. If you are concerned, check with your doctor, pharmacist or nurse. Ask your doctor, pharmacist or nurse for advice before taking any medicines whilst breast-feeding.

## **3. How to take Dapsone**

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

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

The recommended doses are:

• **Adults and adolescents (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 jirovecii* pneumonia: In combination with trimethoprim, 50-100mg daily or 100mg twice weekly or 200mg once weekly.

• **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.

• **Elderly:**

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

**If you take more Dapsone than you should**

If you take more Dapsone 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**

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 and then take the next dose at the right time.

**If you stop taking Dapsone**

Do not stop taking Dapsone without talking to your doctor, pharmacist or nurse. 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, please contact your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, Dapsone 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 also 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 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 national reporting system listed in the Yellow Card

Scheme [www.mhra.gov.uk/yellowcard](http://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**

Tillomed Laboratories Limited  
220 Butterfield, Great Marlings,  
Luton, LU2 8DL  
United Kingdom

**Manufacturer<sup>1</sup>**

Emcure Pharma UK Limited  
Basepoint Business Centre,  
110 Butterfield, Great Marlings,  
Luton, LU2 8DL  
United Kingdom

Tillomed Laboratories Limited  
220 Butterfield, Great Marlings,  
Luton, LU2 8DL  
United Kingdom

Tillomed Pharma GmbH  
Manhagener Allee 36  
22926 Ahrensburg  
Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom	Dapsone 50mg Tablets
	Dapsone 100mg Tablets
Germany	Dapson Tillomed 50mg Tabletten
	Dapson Tillomed 100mg Tabletten

This leaflet was last revised in 03/2018.

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<sup>1</sup> **Only the actual release site will be listed on the marketed product**