

## Daraprim® 25 mg tablets

### Pyrimethamine

#### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions about your illness or your medicine, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

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### 1 What Daraprim is and what it is used for

Daraprim contains a medicine called pyrimethamine. This belongs to a group of medicines called antiprotozoals. They treat infections of the blood caused by parasites.

Daraprim is used:

- to prevent malaria in people living in areas where the malaria parasite (*Plasmodium*) is sensitive to pyrimethamine (Daraprim). It is important that you only take Daraprim if it has been recommended by your doctor, pharmacist or travel clinic. Daraprim is not suitable for all malaria areas.
- to treat infections, caused by a parasite called *Toxoplasma* together with antibiotics called **sulphonamides**. These infections can affect the:
  - brain (encephalitis) and other parts of the body if your immune system is poor. This can be due to AIDS
  - eyes, infection can lead to problems with your eyesight
  - unborn baby, when an infection is passed on from the mother during pregnancy.Ask your doctor if you need to have these conditions explained to you.

### 2 Before you take Daraprim tablets

#### Do not take Daraprim if:

- you are allergic (hypersensitive) to pyrimethamine or any of the other ingredients of Daraprim (see Section 6: Further information)
- you are a woman in the first trimester of pregnancy
- you are a woman who is breast-feeding. Ask your doctor or midwife for advice.
- you are a child under 5 years of age.

Do not take if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Daraprim.

#### Take special care with Daraprim

Check with your doctor or pharmacist before taking this medicine if:

- you have kidney or liver problems
- you have a blood problem called anaemia
- you have ever had fits (seizures).

#### 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. This includes herbal medicines. This is because Daraprim can affect the way some medicines work. Also some other medicines can affect the way Daraprim works.

In particular tell your doctor if you are taking any of the following medicines:

- trimethoprim or co-trimoxazole – used as antibiotics
- proguanil or quinine sulphate – used for malaria/ night cramps
- zidovudine – used to treat HIV infection / AIDS
- medicines for cancer – such as methotrexate, daunorubicin, or cytosine
- lorazepam – used to help you sleep or relax

- warfarin – used to thin your blood
- antacids – used for heart-burn or indigestion

- medicines for diarrhoea which contain an ingredient called kaolin.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Daraprim.

#### Pregnancy and breast-feeding

Do not take Daraprim if you are 12 weeks pregnant or less. It can harm your baby.

If you are more than 12 weeks pregnant, or might become pregnant, talk to your doctor before taking Daraprim.

Do not breast-feed if you are taking Daraprim. Ask your doctor or midwife for advice.

### 3 How to take Daraprim

Always take Daraprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets with a glass of water.

**No medicine for malaria gives complete protection.** You should also ensure you:

- Cover exposed areas of skin
- Use insect repellents and mosquito nets.

#### Malaria

To help prevent infection with malaria the usual dose depends on your age:

- **Adults and children over 10 years** - One tablet once a week
- **Children 5 to 10 years** - Half a tablet once a week
- **Children under 5 years should not take Daraprim**
- Take your first tablet during the week before you travel to the malaria area
- Take a dose each week you are in the area

- Take a dose each week for a further 4 weeks after you leave the malaria area.

#### Toxoplasmosis

Daraprim should always be given with another antibiotic called a sulphonamide and a folic acid (vitamin) supplement.

**Adults and children over 5 years.** To treat infections, caused by *Toxoplasma* you usually:

- Take the medicine for 3 to 6 weeks.
- If you need a further course, you should wait for two weeks between courses.
- To treat infections of the brain (encephalitis) and other organs in people who have a poor immune system or AIDS, the usual dose is:
  - four to eight tablets each day for the first 2 or 3 days
  - then between one and four tablets each day for the rest of the course.
- To treat infections of the eye, the usual dose is:
  - four tablets each day for the first 1 or 2 days
  - then one or two tablets each day for the rest of the course.

**In the unborn baby** Daraprim may stop toxoplasmosis from the mother damaging the unborn baby.

- From week 13 of your pregnancy onwards, the usual dose is: one or two tablets each day.

**Daraprim may cause harm to the baby in the first 12 weeks of your pregnancy. A different medicine should be used until the 13-week of pregnancy.**

**Children under 5 years should not take Daraprim.**

**If you take more Daraprim than you should, talk to a doctor or go to hospital straight away. Take this medicine pack with you.**

#### If you forget to take Daraprim

- If you forget to take a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

### 4 Possible side effects

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

**If you have any of the following side effects or symptoms, talk to your doctor immediately:**

- sore throat, an unexpected illness or skin reaction such as a rash or irritation or breathlessness.

- abnormal bruising, tiredness, weakness or giddiness
- These symptoms may mean that you are suffering from a drop in the number of your blood cells.

This increases your risk of bleeding, bruising and makes you less able to fight infections. Your doctor will be able to confirm this by carrying out a blood test, and if necessary, will give you appropriate treatment.

Daraprim may bring on fits (seizures) in patients who are prone to epilepsy. If you have epilepsy talk to your doctor or pharmacist before taking this medicine. Other side effects include:

**Very common** (affects more than 1 in

10 people)

- anaemia
  - headache
  - vomiting, feeling sick and diarrhoea
- Common** (affects less than 1 in 10 people but more than 1 in 100 people)
- tiredness, weakness, abnormal bruising
  - giddiness
  - weakness
  - change in blood test results

**Uncommon** (affects less than 1 in 100 people but more than 1 in 1000 people)

- fever
  - abnormal skin pigmentation
- Very Rare** (affects less than 1 in 10,000 people)
- change in blood test results, sleepiness, contractions of body muscles
  - sudden onset of high fever, rapid shallow breathing, chills and sweating
  - abdominal pain
  - mouth ulcers on the inside of the cheek
  - red inflamed dry skin
  - malaise

**If you have been prescribed Daraprim and you become unwell during or after your visit to the malaria area, tell your doctor or pharmacist if you cannot think of another reason for feeling unwell.**

If you have been prescribed Daraprim for toxoplasmosis please check the leaflet for the sulphonamide antibiotic you should also have been prescribed. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5 How to store Daraprim

- Keep out of reach and sight of children.
- Do not use Daraprim after the 'use by' date which is stated on the pack. The date refers to the last day of the month.
- Store these tablets below 30°C and inside the original packaging to protect them from light.
- 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 protect the environment.

### 6 Further information

#### What Daraprim contains

- The active substance is pyrimethamine. Each tablet contains 25 mg of the active substance.
- The other ingredients are lactose monohydrate, maize starch, hydrolysed starch, docusate sodium and magnesium stearate.

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