Package Leaflet: Information for the User

Daraprim 25 mg tablets

pyrimethamine

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.

In this leaflet:

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

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 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 What you need to know before you take Daraprim

Do not take Daraprim:

- if you are allergic (hypersensitive) to pyrimethamine or any of the other ingredients of Daraprim (see Section 6: Contents of the pack & other information)
- if you are a woman in the first trimester of pregnancy
- if you are a woman who is breast-feeding. Ask your doctor or midwife for advice.
- if 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.

Warnings and Precautions

Talk to your doctor before taking Daraprim if:

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

Daraprim should always be given with a folic acid (vitamin) supplement.

Other medicines and Daraprim
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if you are taking any of the following medicines:
- trimethoprim or cotrimoxazole – used as antibiotics
- proguanil or quinine sulfate – 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.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed. Dizziness and seizures have been reported by patients taking Daraprim. If you experience these, caution should be exercised in driving and using machinery.

Daraprim contains lactose
Daraprim contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before using this medicine.

Daraprim contains sodium
Daraprim contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3 How to take Daraprim

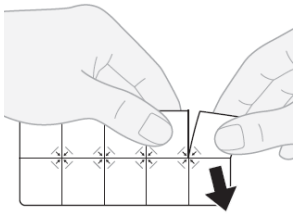
Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets with a glass of water.

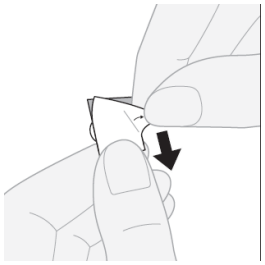
Taking out a tablet

These tablets come in special packaging to prevent children removing them.

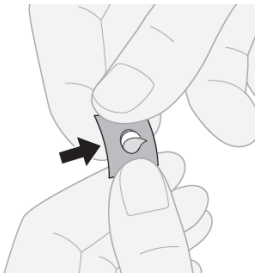
1. **Separate one tablet:** tear along the cutting lines to separate one “pocket” from the blister.



2. Peel back the outer layer: starting at the corner, lift and peel over the pocket.



3. Push out the tablet: gently push one end of the tablet through the foil layer.



Toxoplasmosis
Daraprim should always be given with another antibiotic, for example a sulphonamide, and a folic acid (vitamin) supplement.

Adults and children over 6 years.
- To treat infections caused by Toxoplasma, 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:
  - two tablets, twice a day, for the first 2 days
  - then two tablets each day for the rest of the course.
- **Daraprim may cause harm to the baby in the first 12 weeks of your pregnancy. A different medicine should be used until the 13th week of pregnancy.**

Adults and adolescents who have a poor immune system or AIDS.
- To treat infections caused by Toxoplasma, the usual dose is based on body weight:
- Less than 60 kg:
  - eight tablets on the first day
  - then two tablets each day for the rest of the course.
- 60 kg or more:
  - eight tablets on the first day
  - then three tablets each day for the rest of the course.

Children from 5 to 6 years.
- To treat infections caused by Toxoplasma, the usual dose is based on body weight:
  - 2 mg/kg bodyweight (maximum of two tablets) on the first day
  - then 1 mg/kg bodyweight (maximum of one tablet) each day for the rest of the course.

Children under 5 years should not take Daraprim.

If you take more Daraprim than you should
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 dizziness

  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 (may affect more than 1 in 10 people)
- decrease in the number of red blood cells (anaemia). You may feel tired or weak
- headache
- vomiting, feeling sick and diarrhoea
- rash

Common (may affect less than 1 in 10 people but more than 1 in 100 people)

- decrease in the number of blood platelets (cells that help blood to clot). The blood may take longer to clot than normal. You may notice this if you have a nosebleed or cut yourself
- dizziness
- decrease in the number of white blood cells. This may affect your ability to fight infections

Uncommon (may affect less than 1 in 100 people but more than 1 in 1000 people)
- fever
- abnormal skin pigmentation

Very Rare (may affect less than 1 in 10,000 people)
- decrease in the number of all types of blood cells. Symptoms can include: tiredness, weakness, rashes or bruising easily, pale skin, rapid heart rate, shortness of breath, bleeding problems such as bleeding of the gums or nosebleeds, infections
- 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

If you have been prescribed Daraprim for toxoplasmosis please check the leaflet for the sulphonamide antibiotic you should also have been prescribed.

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 by searching 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 Daraprim

- Keep this medicine out of the sight and reach 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 Contents of the pack & other 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.

What Daraprim looks like and contents of the pack
Daraprim tablets are white and round with the marking 'GS A3A'. They are packaged in blister packs enclosed in a carton. Available in packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
The Wellcome Foundation Ltd, 79 New Oxford Street, London, WC1A 1DG, United Kingdom
Manufacturer:
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany.
or

Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations), Harmire Road, Barnard Castle, Durham, DL12 8DT, United Kingdom.

Other formats
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:
Product name: Daraprim 25 mg tablets
Reference number: 00003/5026R

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in: October 2024.

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