

[사프리카] 파라맥스정 설명서 (Ver. 영본)

Size : 300 x 150 (mm)
자재관리번호 : 3T200FR00

[정제 영어 설명 페이지]

PYRAMAX[®] 180 mg/60 mg Film Coated Tablets Pyronaridine tetraphosphate and Artesunate

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours or your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pyramax is and what it is used for
2. Before Pyramax is taken
3. How to take Pyramax
4. Possible side effects
5. How to store Pyramax
6. Further information

1. WHAT PYRAMAX IS AND WHAT IT IS USED FOR

Pyramax belongs to a group of medicines known as anti-malarials. Pyramax tablets are used in adults and children weighing 20 kg or more for the treatment of acute, uncomplicated malaria infection caused by parasites called *Plasmodium falciparum* or *Plasmodium vivax*. Pyramax is not suitable for preventing malaria, nor for treating severe malaria (e.g. affecting the child's brain, kidneys, or lungs).

2. BEFORE PYRAMAX IS TAKEN

- Do not take Pyramax if you or your child have allergic (hypersensitive) to pyronaridine tetraphosphate or any of the ingredients listed at the end of this leaflet.
- You are known to have severe kidney disease.
- You have a severe liver disease or you have clinical symptoms of hepatic dysfunction such as nausea or abdominal pain associated with jaundice (yellowing of the eyes and/or skin).

Talk to your doctor or pharmacist before taking Pyramax if you or your child:

- have abnormal hepatic function notably elevated transaminases which can be shown after blood sample analysis,

- are co-infected with hepatitis B or C or HIV,
- are malnourished,
- use concomitant drug such as paracetamol, valproic acid (to treat epilepsy; a neurological disorder), anti-epileptic (to treat HIV) or herbal medicines (referred to as a medicine) containing any of the following: (1) a reduced red blood cell count; (2) signs of anaemia (such as tiredness and lethargy (lack of energy), shortness of breath and a pale complexion),
- suffer from kidney disease.

You should monitor especially in the first 2 weeks after taking Pyramax any clinical signs or symptoms of hepatic dysfunction such as fatigue, nausea, abdominal pain, dark urine, putty or mastic coloured stools, jaundice (yellowing of the whites of the eyes or skin) and itching. Contact your doctor or pharmacist if you or your child experience such symptoms, particularly if you or your child get more than one of them. In this case, your doctor may request blood samples to test and monitor the liver function.

Taking other medicines

Please tell your doctor or pharmacist if the person taking the medicine (you or your child) are taking or have recently taken any medicines, including medicines obtained without a prescription, especially if you are being treated with any of the following:

- drugs used to treat HIV (such as ritonavir)
 - drugs that are used for nervous diseases
 - certain types of antibiotic and anti-fungal agents
 - digoxin
 - dabigatran
 - ketoconazole
 - flecainide
 - metoprolol
 - imipramine
 - dantrolene
 - hepatic remedies
- If you or your child are taking any of these medicines, tell your doctor before taking this medicine as your doctor may need to monitor you or your child more closely or carry out blood tests.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, or there is any possibility that you may be pregnant (even if you are not sure) or become aware that you are pregnant while taking Pyramax, or soon after. Pyramax must not be used during the first three months of pregnancy unless your doctor has advised you that there is no alternative. In the later stages of pregnancy, you can take

Pyramax only if your doctor feels that alternative medicines would be unsuitable. Your doctor will discuss with you the potential risk of taking Pyramax during pregnancy and will want to keep seeing you until the baby is born.

The doctor will report your pregnancy to the manufacturer of the medicine. This is to ensure that you can understand any effects that the treatment may have on the pregnancy and the baby. If possible, you should not breastfeed while you are taking Pyramax as this medicine can pass into breast milk.

Driving and using machines

Pyramax may make you or your child feel dizzy, weak or sleepy. If this happens to you, you are advised not to drive or use any machines.

Important information about some of the ingredients of Pyramax

- Pyramax contains Tartrazine (E102) and Sunset yellow FCF (E110) which may cause allergic reactions which may show as:
 - Flushing (reddening) of the skin especially around the face and upper chest)
 - The appearance of wheals / urticaria (itchy blisters)
 - Breathlessness
 - Feeling faint or light-headedness

3. HOW TO TAKE PYRAMAX

Always take Pyramax exactly as your doctor has told you and always finish the whole course of treatment. You should check with your doctor or pharmacist if you are not sure.

Taking Pyramax

- the tablets are to be swallowed whole.
- if you or your child are sick (vomit) within 30 minutes of taking this dose take a repeated dose.
- if you or your child are sick (vomit) after taking the repeated dose do not take any more tablets and tell your doctor who may need to give you or your child an alternative medicine to treat the malaria.
- if you or your child have mild diarrhoea, you or your child can continue to take Pyramax normally. However, if you suffer from severe diarrhoea you should speak to your doctor who may have to treat you or your child with an additional or alternative anti-malarial.

How much to take

-the recommended dose should be taken once a day for three days without a break. You should try

to take the medicine at the same time of day.

- the number of tablets you can take depends on your weight:
 - 20 kg to less than 24 kg body weight: take one tablet daily for three days
 - 24 kg to less than 49 kg body weight: take two tablets daily for three days
 - 45 kg to less than 65 kg body weight: take three tablets daily for three days
 - 65 kg body weight or greater: take four tablets daily for three days

Pyramax tablets should not be given to children who weigh less than 20 kg. A granule formulation is available if your child weighs between 5 to under 20 kg.

No special precautions or dosage changes are considered to be necessary if you have been told that you or your child have reduced liver function or reduced kidney function. This is because of the short three day course of treatment.

If you or your child take more Pyramax than you should
If you have accidentally taken too many tablets, contact your doctor as soon as you can.

If any of the Pyramax doses are forgotten
Try to make sure you or your child do not miss any doses. If however, you forget a dose of Pyramax, take or give to your child the missed dose as soon as you remember and then the next dose 24 hours later. Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking Pyramax
Make sure you or your child finish the entire course of the treatment, even if you feel better, since the malaria infection may otherwise return. Therefore, do not stop taking your medicine unless your doctor tells you to. If you or your child stop taking Pyramax before the course is finished for any reason other than because your doctor has told you to, you must contact your doctor who will want to give you or your child alternative treatment.

Always follow your doctor's instructions carefully, and complete the course of medication. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

- the number of cells that help blood clotting (platelets) may change. If they fall too much you or your child may find that bleeding takes longer to stop
- Changes in your blood sugar may occur
- Less commonly your doctor or nurse may find:
 - Sugar or protein in the urine or occasional white cells
 - presence of ketones in the urine (ketonuria)
- small changes in blood pressure
- Rarely:
 - irregularity in your heart rhythm (arrhythmia)
 - If any of the side effects become troublesome, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE PYRAMAX

Keep out of the reach and sight of children. Do not use Pyramax after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package. Do not use Pyramax if you notice that the packaging is damaged or shows signs of tampering. Medicines should not be disposed of via wastewater or household waste. Ask your healthcare provider how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

- The active substances are pyronaridine tetraphosphate and artesunate.
- The other ingredients are:
 - Tablet - Microcrystalline cellulose, Croscopolone, methylcellulose, Macrogol 6000, Sunset yellow FCF (E110) (see section 2)
 - Film coating - Hypromellose, Titanium dioxide, Tartrazine (E102), Macrogol 6000, Sunset yellow FCF (E110) (see section 2)

What Pyramax looks like and contents of the pack

Pyramax tablets are round, orange coloured tablets. Pyramax tablets are available in tropical PVC aluminium foil blisters containing 9 tablets. The blisters are packed into cartons containing one or 10 blisters.

Manufacturer

 SHIN POONG PHARM. CO., LTD.
70, Sandan-ro 19beon-gil, Danwon-gu, Ansan-si, Gyeonggi-do, Korea

Information issued : Jun. 28, 2019

3T200FR00

