

**[사프리카] 피라맥스그립 설명서 (Ver. 영월)**

수정사항  
 1. 기재권리번호 변경  
 2. Information issued 변경

Size : 300 x 150 (mm)  
 자재권리번호 : 3G200FR00

[과립 영어 설명 페이지]

# PYRAMAX®

60 mg/20 mg Granules for oral suspension  
 Pyronaridine tetrakisphosphate and Artesunate

## Read all of this leaflet carefully before your child starts 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as 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 Pyramax is taken
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 antimalarials. Pyramax granules are used in children and infants weighing 5 kg or more up to 20 kg for the treatment of acute uncomplicated malarial 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

**Pyramax should not be given to your child if your child**

- is allergic (hypersensitive) to pyronaridine tetrakisphosphate, artesunate, or any of the other ingredients of Pyramax listed at the end of this leaflet.
- is known to have severe kidney disease.
- has a severe liver disease or has clinical symptoms of hepatic dysfunction such as nausea or abdominal pain associated with jaundice (yellowing of the eyes and/or skin).

### To be special care with Pyramax

Talk to your doctor or pharmacist before Pyramax is taken if your child

- has abnormal hepatic dysfunction notably elevated transaminases which can be shown after blood sample analysis,

- is co-infected with hepatitis B or C or HIV.

- is malnourished.
- is taking concomitant drug such paracetamol, valproate (to treat epilepsy), a biological (steroids), or any other medicine (see also Take other medicines (see also Take other medicines)).
- is anaemic (to have a low red blood count - signs of anaemia include tiredness and lethargy (lack of energy), shortness of breath and a pale complexion).

You should monitor your child especially in the first 2 weeks after Pyramax intake any clinical signs or symptoms of changed liver function 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 your child experiences such symptoms, particularly if your child gets 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 (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 zidovudine)
  - drugs used to treat malaria (such as quinine)
  - drugs used to treat fungal diseases
  - certain types of antibiotic and anti-fungal agents
  - digoxin
  - diltiazem
  - ketoconazole
  - flecainide
  - metoprolol
  - amitriptyline
  - domipramine
  - herbal remedies
  - valproate
- If the person taking the medication is taking any of these medicines, tell your doctor before giving this medicine as your doctor may need to monitor your child more closely or carry out blood tests.

### Pregnancy and breast-feeding

Not applicable

### Driving and using machines

Not applicable

**Important information about some of the ingredients of Pyramax**  
 Pyramax contains Tartrazine (E102) and Sunset yellow FCF (E10) 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)
- Skin rashes
- Feeding pain or light-headedness

### 3. HOW PYRAMAX IS TAKEN

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 granules for oral suspension should be taken, as instructed by your doctor in a small amount of water as described below under Administration of Pyramax Granules for oral suspension.  
 - the granules can be taken with or without food.  
 - if your child is sick (vomits) within 30 minutes of taking the first dose, take a repeat dose.  
 - if your child is sick (vomits) after taking the repeat dose do not take any more Pyramax and speak to your doctor who may need to give your child an alternative medicine to treat the malaria.  
 - if your child has mild diarrhoea, your child can continue to take Pyramax normally. However, if your child suffers from severe diarrhoea, you should speak to your doctor who may have to treat your child with an additional or alternative antimalarial.

### How much to give

- the recommended dose should be taken once a day for three days without a break. You should try to give the child the medicine at the same time of day.  
 - the number of sachets of granules for oral suspension which should be taken depends on the child's weight:  
 - 5 kg to less than 8 kg body weight: give one sachet daily for three days  
 - 8 kg to less than 15 kg body weight: give two sachets daily for three days  
 - 15 kg to less than 20 kg body weight: give three sachets daily for three days  
 A tablet formulation is available if your child weighs more than 20 kg.

### Administration of Pyramax Granules for oral suspension

Add a small amount of water (approximately 10 ml i.e. 2 teaspoons) into a small cup. Put the contents of the required number of sachets (based on the weight of the child) into the cup and gently stir the granules into the water. The resulting mixture will not dissolve. The patient should swallow the suspension immediately. Add a small amount of water (approximately 10 ml i.e. 2 teaspoons) to the

cup to mix any remaining granules and the suspension should then be immediately swallowed by the patient. It is recommended to repeat this step until the patient has swallowed all the granules and no granules remain in the cup. On shaking the oral suspension should be used for the oral suspension. No studies have been conducted on administration with feeding tubes. Caution is needed to minimise the risk of inhaling the granules with very young children.

### Important:

- Give dose by weight.
- Administrez la dose selon le poids.

<p>5kg~8kg 3 sachets</p>	<p>8kg~15kg 6 sachets</p>	<p>15kg~20kg 9 sachets</p>
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No special precautions or dosage changes are considered to be necessary if you have been told that your child has a fever, flu, or a reduced kidney function. This is because of the short three day course of treatment.

**If your child takes more Pyramax than he/she should**  
 If your child has accidentally taken too many granules, contact your doctor as soon as you can.  
**If any of the Pyramax doses are forgotten**  
 Try to make sure you do not miss any doses. If however, you forget to give to your child a dose of Pyramax, give the missed dose as soon as you remember and then the next dose 24 hours later. Do not give a double dose to make up for a forgotten dose.

**If your child stops taking Pyramax**  
 Make sure your child finishes the entire course of the treatment, even if they feel better, because the malaria infection may otherwise return. Therefore, do not stop the medicine unless your doctor tells you to.

If you stop giving 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 advise you on the appropriate treatment. Always follow the 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**  
 Although allergic reactions to Pyramax are very uncommon, you do experience the following symptoms of an allergic reaction:

- sudden wheezing, tightness of the chest or throat, difficulty swallowing or breathing
- swelling of the eyelids, face, lips, tongue or other part of the body

**Tell your doctor immediately** or go to the nearest hospital or clinic immediately and take this leaflet with you.

You should also tell your doctor if your child experiences any of the following symptoms (particularly if your child get more than one of them): fatigue, nausea, abdominal pain, dark urine, putty or mastic (very light coloured) stools, jaundice (yellowing of the whites of the eyes or skin) and itching.

**Other possible side effects that you may notice are:**

- headache
- feeling or being sick
- abdominal pain
- Uncommon (affecting less than 1 in 100 patients)
  - feeling dizzy or weak
  - tiredness, sleeping problems
  - upset stomach, poor appetite, diarrhoea or constipation
  - fever, excessive sweating, cough, respiratory infection, bladder infection or skin infection
  - sore mouth or throat, aching muscles
  - tingling and/or numbness
  - decreased sense of taste
  - heaviness in the abdomen that may be due to an enlarged liver or enlarged spleen
  - rash, itching, cutaneous reaction
- Rare (affecting less than 1 in 1000 patients)
  - runny eyes or runny nose
  - altered hearing or ringing in the ears
  - feeling shivery, fever
  - joint, back, or chest pain
  - nose bleed or coughing up blood
  - asthma

### Other side effects:

There are side effects that you may not notice as your doctor may want to do more tests to check that these abnormalities return to normal.  
 Common side effects which may show up in blood tests, include:  
 - changes in liver enzymes  
 - changes in certain elements of white blood cells  
 - anaemia or worsening of anaemia

- the number of cells that help blood clotting (platelets) may change. If they fall too much you may find that bleeding takes longer to stop
- changes in blood sugar may occur
- normally your doctor or nurse may find:
  - low iron 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**  
 Do not use Pyramax after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of the 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

**What Pyramax contains**  
 The active substances are pyronaridine tetrakisphosphate and artesunate.  
 The other ingredients are:  
 - Granules for oral suspension - Mannitol, Talc, Ethyl cellulose, Macrogol 6000, Hypromellose 2910, Tartrazine (E102), Sunset yellow FCF (E10), Acesulfame potassium (see section 2)

### What Pyramax looks like and contents of the pack

Pyramax granules for oral suspension are orange coloured granules.  
 Pyramax granules for oral suspension are packaged in sachets consisting of layers of polyester, aluminium and polyethylene/Surllyn. Each carton contains 90 sachets.

### Manufacturer

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