

包材名称	说明书_注射用青蒿琥酯说明书		
包材SAP代码	112013957		
药品/包装规格	30mg&60mg&120mg&180mg		
尺寸	140*422mm		
材质	70g双胶纸		
要求	折后成型尺寸140*40mm，偏差±1mm；成型后包材识别码(二维码)居中朝上		
备注	英法06版		
修改内容	升级与WHO挂网版一致，调整尺寸，重新排版，将MAH由上海复星医药产业发展有限公司修改为桂林南药股份有限公司		
包装设计稿 生效日期：		分 发 部 门	QC、INJ
设计：黄勇 2024. 09. 04			
复核1:			
复核2:			
RA审核:			
批准:			

色标:

CMYK: 0/0/0/100

65mm

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Argesun®

Artisanate Co-Pack Arginine

The warnings and instructions in this leaflet are intended for the person taking the medicine.

If you use a parent or carer responsible for giving the medicine to someone else such as a child, you will need to apply the instructions accordingly.

Artisanate 30 mg for injection and sodium bicarbonate and arginine injection (sodium bicarbonate 8.4mg/ml, and arginine 1.5mg/ml) for preparation of solution for intravenous or intramuscular injection.

Artisanate 60 mg for injection and sodium bicarbonate and arginine injection (sodium bicarbonate 8.4mg/ml, and arginine 20mg/ml, 3mg/l) for preparation of solution for intravenous or intramuscular injection.

Artisanate 120 mg for injection and sodium bicarbonate and arginine injection (sodium bicarbonate 8.4mg/ml, and arginine 40mg/ml, 6mg/l) for preparation of solution for intravenous or intramuscular injection.

Artisanate 180 mg for injection and sodium bicarbonate and arginine injection (sodium bicarbonate 8.4mg/ml, and arginine 60mg/ml, 9mg/l) for preparation of solution for intravenous or intramuscular injection.

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is this leaflet?

- What Argesun is and what it is used for
- What you need to know before you are given Argesun
- How Argesun is given
- Side effects of this medicine
- How to store Argesun
- Contents of the pack and other information

1. What Argesun is and what it is used for

Argesun is a medicine used to treat severe malaria infection and to control the fever. The medicine is dissolved and is made up into a solution that is injected into a vein or a muscle.

Argesun is used to treat severe malaria infection caused by Plasmodium falciparum spread by the bite of an infected mosquito. Argesun is used when the malaria is caused by a type of malaria parasite called Plasmodium falciparum and when the infection is severe enough that it cannot be treated with medicines by mouth.

Your health care provider will follow the most recent official guidelines on the use of malaria medicines to select the right medicine for your malaria treatment.

2. What you need to know before you are given Argesun

Do not take Argesun if you are allergic to the active substance or any of the other ingredients of this product (see section 6).

Warnings and precautions

After you have been treated with Argesun you might develop the most severe symptoms of your malaria infection you will need to take malaria medicines by mouth to complete the treatment.

Some people treated with this medicine have developed increased breakdown of red blood cells in the body after treatment has been completed. A low red blood cell levels within the first month after therapy. This has been seen most often in small children and teenagers. Your health care provider may carry out blood tests to check for this risk for the first few weeks after treatment.

Taking other medicines

- Tell your health care provider if you are taking any other medicines, including medicines bought without prescription.

Pregnancy and breastfeeding

Severe malaria is especially dangerous during pregnancy, so if you need treatment with Argesun it will be given to you. Use during pregnancy is not expected to cause harm to you or the unborn baby.

A small amount of the medicine enters human breast milk, but if you are well enough to breastfeed this is not expected to cause any problems for your baby. However, there is not enough evidence to protect the child from malaria.

3. How Argesun is given

Argesun is given by injection into a vein or into a muscle (usually the thigh). The dose is based on your weight. Your health care provider will show you the right dose to give. Treatment is given for at least a day until you are well enough to be treated by malaria medicines taken by mouth.

If you have any further questions about the use of this product, ask your health care provider.

4. Possible side effects

All medicines, Argesun can cause side effects, but not everybody gets them. Some of these may be difficult to detect, and may be similar to side effects of the disease itself.

Common side effects (may affect up to 1 in 10 people):

Dizziness, feeling sick, vomiting, light-headedness, headache, sleeplessness, hearing problems or ringing in the ears, slow heart rate (bradycardia), low blood pressure, feeling faint, pain at muscle pain, cough, irritated or runny nose, altered taste, abnormal pain, diarrhoea, loss of liver enzymes (may indicate liver damage), rash, hair loss and pain at injection site.

Uncommon side effects (may affect up to 1 in 100 people):

Anaemia (low red blood cell count, see also below), neutropenia (low levels of white blood cells which are important to fight infections), jaundice (yellowing of the skin), low platelet counts (may lead to bruising, yellowing of eyes or skin (jaundice), reduction in platelets (which are important for blood clotting), severe painful rashes with itchy blisters (allergic reactions).

Rare side effects (may affect up to 1 in 1,000 people):

Inflammation of the liver (hepatitis) and inflammation of the pancreas (pancreatitis).

Very rare side effects (may affect up to 1 in 10,000 people):

Severe reduction in red blood cells, tingling sensation and nerve pain.

Not known (frequency cannot be estimated from the available data):

Abnormal electrical activity of the heart.

Anaemia (low red blood cells) may occur within one month after treatment. It has been reported especially in young children and teenagers. If you feel excessively tired, weak or short of breath up to 4 weeks after treatment, inform your health care provider.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report side effects directly to your national reporting system if one is available.

By reporting side effects you can help to improve the available information on this medicine.

5. How to store Argesun

Keep this medicine out of the sight and reach of children. Store in the original packaging, below 30°C, until it is ready to be used. Create a solid state. The reconstituted solution should be stored below 30°C and the total in-use period should not exceed one hour. Protect from light. Do not refrigerate or freeze.

Avoid excursions above 30°C.

This medicine must not be used after the expiry date stated on the carton, vial or ampoule, after 12°C.

This medicine must not be used if you notice visible signs of deterioration.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 Argesun contains

The active ingredient is artesunate.

The artesunate injection does not contain any other ingredients. The solution for dilution contains 8.4 mg of sodium bicarbonate and 30 mg of arginine per mL of solution.

The other ingredients of the solvent are phosphoric acid (for pH adjustment) and water for injection.

There is too little sodium in solvent to have any effect, even if you are on a low-sodium diet.

What Argesun looks like and contents of the pack

Co-pack of Argesun 30mg:

Artisanate 30 mg powder for injection:

White crystalline powder.

[illegible]