

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**  
**Nivaquine 68 mg/ 5 ml Syrup**  
Chloroquine sulphate

Is this leaflet hard to see or read?  
Phone 01483 505515 for help

sanofi aventis



**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to take Nivaquine Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 Nivaquine is and what it is used for
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**1. What Nivaquine is and what it is used for**



Nivaquine Syrup (called Nivaquine in this leaflet) contains a medicine called chloroquine sulphate. This belongs to a group of medicines called anti-malarials. It works by slowing down the growth and killing malaria parasites in red blood cells.

Nivaquine is used to help stop you getting malaria. Only take this medicine if you have been advised by a healthcare professional that it is suitable for the country and area that you are visiting.

**2. Before you take Nivaquine**



**Do not take this medicine and tell your doctor if:**

- × You are allergic (hypersensitive) to chloroquine or similar medicines or any of the other ingredients of Nivaquine (listed in Section 6 below)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- × You are pregnant (see Pregnancy and breast-feeding below)

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



**Take special care with Nivaquine**  
**Check with your doctor or pharmacist before taking your medicine if:**

- ▲ You have or have ever had fits (epilepsy)
- ▲ You have a rare illness called porphyria. This is especially true if you also drink large quantities of alcohol
- ▲ You have liver problems
- ▲ You have kidney problems
- ▲ You have severe stomach and bowel (gut) problems
- ▲ You have problems with your nervous system
- ▲ You have been told by a doctor that you have problems with your blood
- ▲ You have psoriasis (itchy red, raised patches of skin with silvery scales)

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



**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Nivaquine can affect the way some other medicines work. Also some medicines can affect the way Nivaquine works.

**Nivaquine may increase the effect of the following medicines:**

- Ciclosporin - used to help stop rejection of transplants
- Digoxin - used for heart problems. If you feel sick, you should tell your doctor straight away

**Nivaquine can make the following medicines work less well:**

- Medicines for muscle weakness (myasthenia gravis) such as neostigmine and pyridostigmine
- Medicines used to treat fits (epilepsy)
- Rabies vaccine - used to protect against rabies

**The following medicines can make Nivaquine work less well:**

- Medicines for indigestion and heartburn (antacids) that contain magnesium
  - Kaolin - used to treat loose bowel motions
- You should make sure that there is a 2 hour gap between taking Nivaquine and taking these medicines.

**The following medicines can increase the chance of you getting side effects, when taken with Nivaquine:**

- Mefloquine - used for malaria
- Cimetidine - used for excess stomach acid or stomach ulcers
- Medicines for thinning the blood (anticoagulants) such as warfarin
- Medicines which have an uneven heartbeat as a side effect (such as amiodarone). Nivaquine can increase the chance of this happening

**Pregnancy and breast-feeding**

Do not take this medicine and talk to your doctor if you are pregnant, might become pregnant or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.



**Driving and using machines**

You may feel dizzy or have blurred vision while taking this medicine. If this happens, do not drive or use any tools or machines. Also a rare side effect of taking this medicine is fits (seizures and convulsions). If you suffer from these you should not drive or use any tools or machines.

**Important information about some of the ingredients of Nivaquine**

This medicine contains:

- **Sodium:** This medicine contains 57 mg sodium per 30 ml dose which should be taken into consideration by people on a controlled sodium diet
- **Sucrose:** This medicine contains 20 g of sucrose per 30 ml dose which should be taken into consideration if you have diabetes
- **Methyl parahydroxybenzoate and propyl parahydroxybenzoate:** These may cause allergic reactions which may not happen straight away. If you have been told by your doctor that you can not tolerate some preservatives speak to them before taking Nivaquine

**3. How to take Nivaquine**

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

### Taking this medicine

- Take this medicine by mouth
- Take this medicine on the same day each week
- Start to take this medicine one week before you leave for the area where malaria is present and continue taking it for four weeks after you have left this area

### How much to take

#### Adults and children 12 years and over

- Take a dose of 30 ml syrup once a week
- Infants and children up to 12 years**
- Give a dose of 0.5 ml per kilogram of the child's body weight once a week
- Please ask your doctor, nurse or pharmacist to work out how much Nivaquine to give your child

#### If you take more Nivaquine than you should

If you take more Nivaquine than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: headache, drowsiness, changes to your eyesight, feeling sick or being sick, shallow breathing or being unable to breathe, unusual heartbeat and possibly death.

#### If you forget to take Nivaquine

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose, you are more at risk of getting malaria. Look out for signs of malaria on your return and talk to your doctor immediately if you develop fever or flu like illness within 12 months of returning from an area with malaria.

#### If you stop taking Nivaquine

If you stop taking Nivaquine before the end of your course, you are more at risk of getting malaria. Look out for signs of malaria on your return and talk to your doctor immediately if you develop fever or flu like illness within 12 months of returning from an area with malaria.

#### Tests that you will need if you are taking Nivaquine for long time

- **Blood tests:** If you are taking Nivaquine for a long period of time, your doctor may do regular blood tests. This is to check the number of red blood cells in your blood
- **Eye tests:** Your doctor may do eye checks before starting treatment and every 3-6 months while you are taking Nivaquine. This is to check that your eyesight is normal. Nivaquine can have a permanent effect on your eyes if taken for a long period of time



If you have any further questions on the use of this product, ask your doctor or pharmacist.

### 4. Possible side effects

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

#### Stop taking Nivaquine and see a doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing

#### Stop taking Nivaquine and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- Uneven heartbeats with or without breathlessness, swollen feet, ankles or legs and tiredness. These could be signs of your heart not beating or working properly
- Fits (convulsions). These could be a sign of malaria in the brain
- You may get infections more easily than usual or feel tired, faint, dizzy or have pale skin. These could be signs of a serious blood problem
- Severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. These could be signs of a serious skin problem

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### Tell your doctor as soon as possible if you have any of the following side effects:

- Feeling anxious or confused, being unable to concentrate or seeing or hearing unusual sights and sounds
- Changes in your eyesight including double vision, eye colour changes, difficulty in focusing, changes to the colours you see or worsening eyesight. In some cases, blindness can happen
- Blurred vision that lasts longer than 48 hours. This could lead to permanent damage to your eyes
- Hearing problems and ringing in the ears
- Yellow colouring of the skin and whites of eyes (jaundice), stomach pain or tenderness. These may be signs of problems with your liver. Tests may reveal changes in the way your liver is working

### Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick or being sick, diarrhoea or stomach cramps
- Tingling, burning or very sensitive skin, muscle weakness, cramps or balance problems. These could be signs of problems with your nerves or muscles
- Feeling dizzy, light-headed and faint. This could be due to low blood pressure
- Headache
- Skin that is itchy, lightens in colour or is more sensitive to sunlight.
- Hair loss
- Your psoriasis gets worse
- Darkening of the nails and mucus membranes (lips, mouth, genitals, anus and inner lids of eyes) if Nivaquine is taken for a long time

Talk to your doctor or pharmacist if any of the side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

### 5. How to store Nivaquine

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Nivaquine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Protect 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 to protect the environment.

### 6. Further information

#### What Nivaquine contains

- Each 5 ml of syrup contains 68 mg of the active substance, chloroquine sulphate. This is equivalent to 50 mg of chloroquine
- The other ingredients are sucrose, monosodium glutamate, saccharin sodium, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, peppermint oil, pineapple flavour, caramel and purified water

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

Nivaquine is a straw coloured syrup. It comes in an amber glass bottle containing 100 ml with a child resistant cap.

#### Marketing Authorisation Holder and Manufacturer

##### Marketing Authorisation Holder

Sanofi-aventis  
One Onslow Street, Guildford, Surrey, GU1 4YS, UK  
Tel: 01483 505515; Fax: 01483 535432  
email: uk-medicalinformation@sanofi-aventis.com

##### Manufacturer

A Nattermann & Cie. GmbH, Nattermannallee 1  
D-50829 Cologne, Germany.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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