PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Plaquenil

200 mg film-coated tablets

SANOFI

Active ingredient and its quantity:
Each Plaquenil tablet contains:
Hydroxychloroquine sulfate 200 mg (155 mg base)

Inactive ingredients: See section 6.

Read this leaflet carefully in its entirety before using the medicine.
Keep this leaflet; you may need to read it again.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment and control of symptoms of malaria attacks, treatment of lupus erythematosus and rheumatoid arthritis.

Therapeutic group: The active ingredient belongs to the aminoquinoline group.

2. BEFORE USING THE MEDICINE

☒ **Do not use the medicine if:**
- **you are sensitive (allergic) to hydroxychloroquine, chloroquine or to any of the additional ingredients contained in the medicine (see section 6).**

If you are uncertain whether you are suffering from an allergic reaction to the medicine, consult the pharmacist or doctor. Symptoms of an allergic reaction may include asthma attack, facial swelling, skin rash or hay fever.
- **you suffer from macular degeneration (maculopathy) or have suffered in the past from changes in vision when taking medicines for treatment of rheumatoid arthritis or for treatment of malaria.**
- **Do not use the medicine in children under 6 years of age.**
- **Do not use the medicine for long periods of time in children over 6 years of age.**

Special warnings regarding use of the medicine
Plaquenil can cause severe hypoglycemia, including loss of consciousness, which can be life-threatening. If you suffer from symptoms of hypoglycemia, refer to the doctor immediately, and perform a test for blood sugar levels.
Before treatment with Plaquenil, inform the doctor if:
- you are allergic to quinine.
- you suffer from eye problems.
- you suffer from low blood sugar levels (hypoglycemia). Plaquenil may increase the risk of low blood sugar levels.
- you suffer from one or more of the following conditions:
  - Chloroquine-resistant malaria.
  - Liver or kidney function problems.
  - Diabetes.
  - Gastrointestinal system, central nervous system or circulatory system problems.
  - A disease of the heart muscle.
  - Skin diseases, particularly psoriasis.
  - G6PD enzyme deficiency.
  - Porphyria - a rare blood disease.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:
- Medicines to treat depression.
- Digoxin - to treat heart diseases.
- Medicines to treat diabetes.
- Medicines for the suppression of the immune system, such as cyclosporin.
- Antiarrythmic medicines, such as amiodarone and moxifloxacin.
- Other antimalarial medicines, such as mefloquine.
- Medicines to treat epilepsy.

These medicines may be affected by Plaquenil tablets, or alternatively, affect the way Plaquenil works.

Pregnancy and breastfeeding
If you are pregnant - consult your doctor concerning the risks versus the benefits of taking Plaquenil tablets.
If Plaquenil tablets are taken for long periods of time, there is an increased risk to the fetus. This may cause problems in brain function, hearing, balance and vision.
Consult the doctor concerning the risks versus the benefits if you are breastfeeding.

Driving and using machines
The use of this medicine may impair vision.
Understand how the medicine affects you before driving, operating machines or performing any activity that could be dangerous if your vision is blurred.
Children should be cautioned against riding a bicycle or playing near the road, etc.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain.
The dosage and treatment regimen will be determined by the doctor only.

The usual dosage for adults, unless otherwise specified by a doctor, is:
Rheumatoid arthritis:
2-3 tablets daily. Later in treatment, the doctor may reduce the dosage to 1-2 tablets daily.
Lupus erythematosus:
2-4 tablets daily. Later in treatment, the doctor may reduce the dosage to 1-2 tablets daily.
Treatment of malaria:
The starting dose is 4 tablets. Take another 2 tablets 6-8 hours later. Afterwards, take two additional tablets once daily during the next two days.
Preventive treatment of malaria:
2 tablets once every 7 days. The tablets should be taken on exactly the same day of each week. For example, if the first dose was taken on a Sunday, then each weekly dose should be taken on Sundays.
The treatment should be started 2 weeks before entering the affected area and should be continued for 8 weeks after exiting it.
If treatment cannot be started 2 weeks before entering the affected area, start the treatment with a one-time double dosage (of 4 tablets) divided into 2 doses, with a 6-hour interval between doses. Then, continue with the normal recommended dosage for 8 weeks after exiting the affected area.
Children: The dosage is according to the doctor's instructions only.
Do not exceed the recommended dose.
Do not chew! Swallow the medicine with water or another liquid.
It is advisable to swallow the medicine with a glass of milk or with food in order to prevent stomach irritation.
Tell the medical team that is treating you, like a doctor or pharmacist, that you are taking Plaquenil and whether you are planning to begin taking a new medicine.
Tell the doctor if you are experiencing any of the following symptoms: weakness, shaking, sweating, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. These symptoms may be related to low blood sugar levels.
In the event that you experience one of the symptoms relating to lowered sugar levels, you must immediately increase your blood sugar levels. This can be done by taking one of the following:
- 5-7 jelly candies.
- 3 teaspoons of sugar or honey.
- 0.5 can of soft drink (not diet).
- 2-3 tablets/cubes of concentrated sugar.
- In the event that your next meal or snack will not be within the next 10-15 minutes, you can add carbohydrates, such as a biscuit, fruit or milk - after the initial symptoms pass. Adding these carbohydrates will prevent a secondary decrease of your blood sugar levels.

Make sure that you, your friends, family and colleagues at work can identify symptoms related to decreased sugar levels and know how to treat them.

Tests and follow-up
During treatment, the doctor will refer you for the following tests:
Eye examinations:
The doctor will refer you for a vision test every few months, in order to ensure that there is no change in your vision.
In extremely rare cases, Plaquenil tablets were associated with blindness. This can be avoided by periodic vision tests.
It is recommended to wear sunglasses when out in the sun.
Blood tests:
The doctor will refer you to perform periodic blood tests.
The doctor may monitor your blood sugar levels if you have experienced symptoms associated with decreased sugar levels while taking Plaquenil.

If you accidentally took a higher dosage
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Children are especially sensitive to preparations from the 4-Aminoquinoline group.
Adhere to these instructions even if you do not feel signs of discomfort or poisoning. You may require urgent medical care.
If you took too high a dosage, you may experience headaches, somnolence, visual disturbances or seizures.
These symptoms may occur within 30 minutes of overdose.

If you forgot to take the medicine
If you are being treated with Plaquenil for rheumatoid arthritis or for lupus erythematosus, do not take a double dose. Treatment should be continued as usual the next day.
If you are being treated with Plaquenil for prevention or treatment of malaria, take the dose as soon as you remember and continue the treatment as usual.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Plaquenil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Contact the doctor immediately if you suffer from the following side effects:
- Visual disturbances.
- Impairment of hearing or loss of hearing.
- Suicidal behavior.
- Frequent fever, severe chills, sore throat or mouth ulcers (these may be signs of circulatory system problems).
- Severe symptoms of decreased sugar levels, including confusion, seizures or convulsions and loss of consciousness.
- Blisters on the skin.
- Sensitivity to light.
- Seizures.
- Unusual tiredness.
- Increased muscle weakness.
- Appearance of bleeding or hemorrhages.

Contact the doctor if you suffer from the following side effects:
- Gastrointestinal disturbances, such as: nausea, vomiting, diarrhea, abdominal pains.
- Loss of appetite.
- Muscle weakness.
- Dizziness.
- Ringing in the ears.
- Headache.
- Nervousness.
- Skin rash and itching.
- Hair loss.
- If you suffer from psoriasis, you are more likely than other patients taking Plaquenil, to suffer from skin side effects.
- Weakening of the heart muscle (cardiomyopathy) which causes difficulty in breathing, cough, high blood pressure, swelling, increased heart rate and low amount of urine.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Shelf life after opening: According to the expiry date (exp. date) that appears on the package.
Storage conditions: Store at a temperature under 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Starch, Dibasic Calcium Phosphate, Opadry White (YS-1-7443), Magnesium Stearate, Polyethylene Glycol (PEG 4000), Carnauba Wax, Tekprint SB-9014SD Black Ink, Film-coating Water.

What the medicine looks like and the contents of the package:
White to off-white peanut-shaped tablets, marked with black ink. The package contains 100 tablets.

License holder: sanofi-aventis Israel ltd.,
P.O. Box 8090, Netanya 4250499.

Name of manufacturer: Sanofi Winthrop Industrie, France.

This leaflet was checked and approved by the Ministry of Health in June 2014.

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

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 449623782.