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

Active ingredient and its quantity:

Each Plaquenil tablet contains: Hydroxychloroquine sulfate 200 mg (155 mg base)

Inactive and allergenic ingredients in the preparation: See section 6 "Further information".

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 "Further information").

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.
- you have a heart rhythm disorder.
- 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 (low blood sugar levels), including loss of consciousness, which can be life-threatening. If you suffer from symptoms of hypoglycemia (see section 3 "How should you use the medicine?"), refer to the doctor immediately, and perform a test for blood sugar levels.

Before treatment with Plaquenil, inform the doctor if:

- you are taking any other medicine for any medical condition.
- you are allergic to quinine.
- you have allergies to any of the ingredients listed in section 6 "Further information" at the end of this leaflet.
- you suffer from eye problems.
- you suffer from hypoglycemia. Plaquenil may increase the risk of low blood sugar levels.
- you suffer from an inactive chronic hepatitis B virus infection. you suffer or have suffered from one or more of the following
- conditions: - Chloroquine-resistant malaria.
- Liver or kidney function problems.
- Diabetes.
- Stomach, brain (neurological disorders) or circulation problems.
- Heart muscle disease.
- Skin diseases, particularly psoriasis, which is a type of itchy rash.
 G6PD enzyme deficiency deficiency of a chemical substance that leads to the breakdown of sugar in the body.
- Porphyria a rare blood pigment disease.
- Porphyria cutanea tarda (PCT) a rare disorder of painful blisters on the skin.

Serious skin reactions

- Serious skin reactions have been reported with the use of Plaquenil.

- Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by flu-like symptoms such as fever, headache and body ache. The rash may progress to widespread blistering and
- peeling of the skin.
- If you develop these skin symptoms, stop taking Plaquenil and contact the doctor immediately.

Mental problems

Certain people treated with Plaquenil may experience mental problems, such as irrational thoughts, anxiety, hallucinations, feeling confused or depressed, including thoughts of self-harm or suicide, even in people who did not have similar problems in the past. If you or others around you notice any of these side effects (see section 4 "Side effects"), seek

immediate medical assistance and discontinue treatment if you have thoughts of self-harm or suicide.

• Talk to the doctor if you have a rare illness called porphyria which affects your metabolism.

Muscle and nerve disorders

Hydroxychloroquine may cause muscle and nerve disorders. Caution must be exercised when taking this medicine for a long time; your doctor will occasionally check for muscle weakness, numbness and pain. **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.

Sunglasses are recommended upon exposure to 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

Plaquenil. Drug interactions If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the

symptoms associated with decreased sugar levels while taking

- **doctor or pharmacist.** Especially inform the doctor or pharmacist if you are taking:
- Medicines to treat depression including the herbal preparation *Hypericum* (St. John's wort).
- Digoxin, flecainide, propafenone 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.
 Medicines to treat epilepsy, such as carbamazepine and
- phenobarbital.
- Tamoxifen (a medicine to treat breast cancer).
- Anti-infective medicines.
 Some antibiotics used for bacterial infections (such as moxifloxacin, azithromycin, clarithromycin, erythromycin, roxithromycin). Taking these antibiotics at the same time as hydroxychloroquine may increase the chance of you getting side effects that affect your heart which
- could be life-threatening. - Medicines that may affect the blood.
- Medicines that may affect the eyes.
 - Antacids containing magnesium or kaoline or cimetidine, used to neutralize stomach acid.
- Itraconazole, an antifungal medicine.
- Rifampicin (antibiotic).
- Grapefruit juice.
- Anticoagulants, such as dabigatran and clopidrogel.
- Medicines to treat high cholesterol, such as gemfibrozil, statins.

Ritonavir (a medicine to treat HIV).
 These medicines may be affected by Plaquenil tablets, or alternatively, affect the way Plaquenil works.

Pregnancy and breastfeeding

Avoid using Plaquenil during pregnancy except when, in the judgement of the doctor, the potential benefit outweighs the potential hazards. 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.

There are very limited data on the safety in the breastfed infant during long-term treatment with Plaquenil. The active ingredient (hydroxychloroquine) is excreted in breast milk and it is known that infants are extremely sensitive to the toxic effects.

Do not use Plaquenil if you are breastfeeding, unless your doctor thinks that the benefit exceeds the risks.

If you are pregnant, think you may be pregnant or are planning to become pregnant or are breastfeeding, consult your doctor or pharmacist before taking any medicine. The doctor will discuss with you whether Plaquenil is suitable for you.

Driving and using machines

Plaquenil may cause dizziness. The use of this medicine may impair vision.

Make sure you know 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 the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage for adults, unless otherwise specified by a doctor,

Rheumatoid arthritis:

2-3 tablets daily. Later in the treatment, the doctor may reduce the dosage to 1-2 tablets daily.

sleeping difficulties, delusions, hallucinations, mood changes, elation

• Frequent fever, severe chills, bruises, sore throat or mouth ulcers (these

• Liver problems. Symptoms may include a general feeling of being

unwell, with or without jaundice (yellowing of the skin and eyes),

• Rare cases of liver failure have been reported (including fatal cases).

• Rash with a fever and flu-like symptoms and enlarged lymph nodes.

• Blistering, widespread scaly skin, pus-filled spots, together with fever.

• Blistering or peeling of the skin around the lips, eyes, mouth, nose,

symptoms of a condition called Stevens-Johnson syndrome (SJS).

Multiple skin lesions, itching of the skin, fever and a general ill feeling.

These could be symptoms of a condition called TEN (toxic epidermal

• Skin reaction including reddish-purple color, raised, painful sores,

particularly on your arms, hands, fingers, face and neck, which may

also be accompanied by fever. These could be symptoms of a condition

Contact the doctor if you suffer from the following side effects:

· Gastrointestinal disturbances, such as nausea, vomiting, diarrhea,

• Weakening of the heart muscle (cardiomyopathy) which leads to

If you suffer from psoriasis, you are more likely to suffer from skin side

If a side effect occurs, if one of the side effects worsens, or if you

suffer from a side effect not mentioned in the leaflet, consult

Side effects can be reported to the Ministry of Health by clicking on

the link "Report Side Effects of Drug Treatment" found on the Ministry

of Health homepage (www.health.gov.il) that directs you to the online

Avoid poisoning! This medicine, and any other medicine, should be kept

in a safe place out of the reach and sight of children and/or infants in

Do not induce vomiting unless explicitly instructed to do so by the

Do not use the medicine after the expiry date (exp. date) that appears

Shelf life after opening: According to the expiry date (exp. date) that

Starch, dibasic calcium phosphate dihydrate, ready to use white colorant,

White to off-white peanut-shaped tablets. The package contains 100

License holder and importer and its address: sanofi-aventis Israel

This leaflet does not contain all the information about your medicine.

If you have any questions or are not sure about anything, please ask

Registration number of the medicine in the National Drug Registry of

What the medicine looks like and the contents of the package:

on the package. The expiry date refers to the last day of that month.

In addition to the active ingredient, the medicine also contains:

magnesium stearate, polyethylene glycol 400, carnauba wax.

form for reporting side effects, or by entering the link

Storage conditions: Store at a temperature under 25°C.

Revised in October 2023 according to MOH guidelines.

5. HOW SHOULD THE MEDICINE BE STORED?

breathing difficulties, cough, hypertension, swelling, increased heart

genitals, hands or feet, flu-like symptoms and fever. These could be

These could be symptoms of a condition called AGEP (acute generalized

These could be symptoms of a condition called DRESS (drug reaction

may be signs of problems in the circulatory system).

dark urine, nausea, vomiting and/or abdominal pain.

• Kidney problems due to accumulation of phospholipids.

Severe symptoms of hypoglycemia, including:

with eosinophilia and systemic symptoms).

or overexcitement.

- confusion.

necrolysis).

• Seizures.

• Changes in heart rhythm.

- seizures or convulsions.

- loss of consciousness

exanthematous pustulosis)

called Sweet's syndrome

Additional side effects:

Sensitivity to light.

Unusual tiredness.

abdominal pains

Loss of appetite.

Muscle weakness

• Ringing in the ears.

• Skin rash and itching.

rate and decreased amount of urine.

https://sideeffects.health.gov.il

order to avoid poisoning

appears on the package.

6. FURTHER INFORMATION

ltd., P.O. Box 8090, Netanya

the Ministry of Health: 449623782

effects than other patients taking Plaquenil

• Dizziness

Headache

• Hair loss.

the doctor.

doctor

tablets.

vour doctor.

• Nervousness.

Lupus erythematosus: 2-4 tablets daily. Later in the treatment, the doctor may reduce the

dosage to 1-2 tablets daily.

<u>Treatment of malaria</u>: 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:

- 3 teaspoons of sugar or honey.

how to treat them.

4-amínoquinoline group.

- 1/2 can of a soft drink (not diet)

- 2-3 tablets/cubes of concentrated sugar.

second decrease of your blood sugar levels.

If you accidentally took a higher dosage

or poisoning. You may need urgent medical care.

somnolence, visual disturbances or seizures.

If you forgot to take the medicine

take the next dose at the usual time.

continued as usual the next day.

the doctor or pharmacist.

not suffer from any of them.

emergency medical care:

• Impairment of hearing or loss of hearing.

• Thoughts of self-harm or suicide

pharmacist.

4. SIDE EFFECTS

Serious side effects:

Visual disturbances.

Suicidal behavior.

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 leaving 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 leaving the affected area. Children: The dosage is according to the doctor's instructions only.

Do not exceed the recommended dose.

There is no information about crushing or pulverizing the tablet. Do not chew! Swallow the medicine with water or another liquid. It is advisable to swallow the medicine with a glass of milk or food to prevent stomach irritation.

Tell the medical team that is treating you, such as a doctor or pharmacist, that you are taking Plaquenil and also if you are supposed to start taking a new medicine.

Tell the doctor if you experience any of the following symptoms: weakness, shaking, sweating, headache, dizziness, lack of concentration, tearing or crying, irritability, hunger and numbness around the lips and fingers. These symptoms may be related to low blood sugar levels (hypoglycemia).

If you experience any of the symptoms of hypoglycemia, you must immediately raise your blood sugar levels. This can be done by taking one of the following: - 5-7 jelly candies.

If you don't plan a meal or snack within the next 10-15 minutes.

add carbohydrates such as a biscuit fruit or milk after the initia

symptoms have passed. Adding these carbohydrates will prevent a

Make sure that you, your friends, family and colleagues at work can

identify the symptoms related to decreased sugar levels and know

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

Adhere to these instructions even if you do not feel signs of discomfort

If you took too high a dosage, you may experience headaches,

If you are being treated with Plaquenil for rheumatoid arthritis or for

lupus erythematosus, do not take a double dose. Treatment should be

If you are taking Plaquenil to treat or prevent malaria, take the dose as

If it is almost time for the next dose, skip the forgotten dose and

Even if there is an improvement in your health condition, do not

stop treatment with the medicine without consulting the doctor or

Do not take medicines in the dark! Check the label and the dose

If you have further questions regarding use of the medicine, consult

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

Contact the doctor immediately or proceed to a hospital emergency

room if you notice the following side effects; you may need

Feeling depressed, nervous or anxious, feeling confused, agitation,

each time vou take medicine. Wear glasses if vou need them.

Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

These symptoms may occur within 30 minutes of overdose.

soon as you remember and continue treatment as usual