יוני, 2022

Plaquenil Film Coated Tablets

חומר פעיל:

Hydroxychloroquine sulfate 200mg

ההתוויה המאושרת:

Plaquenil is indicated for the suppresive treatment and treatment of acute attacks of malaria due to Plasmodium vivax, p. malaria. p. ovale and susceptible strains of p. falciparum.
It is also indicated for the treatment of discoid and systemic lupus erythomatosus and rehumatoid arthritis.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לרופא.

העדכונים העיקריים הינם:

4.6 FERTILITY, PREGNANCY AND LACTATION
Effects on fertility

There are no animal data on hydroxychloroquine action on fertility.

Only limited reproductive toxicity data are available~~Animal studies showed an impairment of male fertility~~ for hydroxychloroquine, therefore chloroquine data are considered due to the similarity of structure and pharmacological properties between the 2 products.

A study in male rats showed a decrease in testosterone levels, weight of testes, epididymis, seminal vesicles and prostate after 30 days of oral treatment with chloroquine at 5 mg/day. In another rat study with chloroquine the male fertility rate was decreased after 14 days of intraperitoneal treatment at 10 mg/kg/day.

~~, a parent drug (see Section 5.3).~~ There are no data in humans.

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Use in pregnancy
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In animal studies on chloroquine, embryo-fetal developmental toxicity was shown at very high, supratherapeutic doses (ranging from 250 to 1500 mg/kg bodyweight).
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5.3 PRECLINICAL SAFETY DATA

Genotoxicity

~~**Reproductive toxicity**~~

~~Only limited preclinical data are available for hydroxychloroquine, therefore chloroquine data are considered due to the similarity of structure and pharmacological properties between the 2 products.~~
Based on the standard genotoxicity studies conducted, hydroxychloroquine is not considered to present a genotoxic risk to humans.
Hydroxychloroquine is not mutagenic in the bacterial reverse mutation (Ames) test.

~~In animal studies on chloroquine, embryo-foetal developmental toxicity was shown at very high, supratherapeutic doses (ranging from 250 to 1500 mg/kg bodyweight).~~
~~A study in male rats showed a decrease in testosterone levels, weight of testes, epididymis, seminal vesicles and prostate after 30 days of oral treatment with chloroquine at 5 mg/day. In another rat study with chloroquine the male fertility rate was decreased after 14 days of intraperitoneal treatment at 10 mg/kg/day.~~

It showed no clastogenicity or aneugenicity in the *in vivo* micronucleus test in rats following oral administration. Hydroxychloroquine was weakly positive in human lymphocyte micronucleus assay *in vitro* in the absence of metabolic activation but was negative in the presence of metabolic activation.

~~***Genotoxicity***~~
~~There are limited data on hydroxychloroquine genotoxicity. Chloroquine is reported in the literature to elicit both gene mutations and chromosomal/DNA breaks in some in vitro systems but not others and in in vivo studies using rodents when dosed via the intraperitoneal route. Chromosomal effects were not observed in vivo when chloroquine was administered orally.~~

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700 .

להלן הקישור לאתר משרד הבריאות: https://www.gov.il/he/service/israeli-drug-index

בברכה,
חברת סאנופי-אוונטיס ישראל בע"מ