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7456

SANDOZ

Hydroxychloroquine Sulfate Tablets, USP

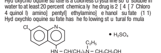
Rx On y

Hydroxychloroquine Sulfate Tablets, USP

Rx only

DESCR PT ON

Hyd oxychlo oquine su fate is a colorless crysta line so d soluble in water to at least 20 percent chemica ly he drug is 2 [4 [7 Chloro 4 quinol l) amino] pentyl] ethylamino] e hanol su fate (1 1) Hyd oxychlo oquine su fate has he fo lowing st u tural fo mula



$C_{18}H_{26}ClN_3O \cdot H_2SO_4$ M.W. 433.96

Ea h tablet for oral administra ion contains 200 mg hydroxychlo oquine su fate (equivalent to 155 mg hydroxychloroquine) Inactive ingredients Dibasic calcium pho phate h droxypropyl ce lulose hyd oxypropyl me hylce lulose magnesium stearate polyethylene gly ol povidone sodium bicarbonate and itanium diox de

CL N CAL PHARMACOLOGY

Pharmacokinetics

Fo lowing a single 200 mg o al dose of hyd oxychloroquine sulfate to hea thy males the mean peak blood concentration of hyd oxychloroquine was 129 6 ng/mL reached in 3 26 hou s with a half ife of 537 hours 22 4 days) In the same study he plasma peak concentration was 50 3 ng/mL eached in 3 74 hours with a half l fe of 2963 hours 123 5 days) Urine hydroxychloroquine levels were s i l detectable after 3 mon hs w th approximately 10% of he dose excreted as the pa ent drug Resu ts following a single dose of a 200 mg tablet versus i v infusion (155 mg) demonstrated a ha f ife of about 40 days and a large volume of distr bu ion Peak blood concentrations of metabo ites were obse ved at the same time as peak levels of hydroxychloroquine The mean fraction of he dose absorbed was 0 74 After administration of single 155 mg and 310 mg intravenous doses peak blood concentrations ranged from 1161 ng/mL to 2436 ng/mL (mean 1918 ng/mL) following the 155 mg infusion and 6 months fo lowing he 310 mg infusion Pharmacokinetic pa ameters were not sign ficantly different over the therapeutic dose range of 155 mg and 310 mg indica ing inear kinetics

Following chronic oral administ ation of hydro ychloroquine sign ficant levels of th ee metabo tes desethy hydroxychloroquine (DHCQ) desethylchlo oquine (DCQ) and b desethy hydroxychloroquine (BDCQ) have been found in plasma and blood w th DHCQ being the major metabol te The absorp ion ha f ife was appro imately 3 to 4 hou s and he te minal ha f fe anged from 40 to 50 days The long ha f l fe can be a t ibuted to extensi e issue uptake rather than through dec ea ed ex retion Peak plasma levels of hydroxychloroquine we e seen in about 3 to 4 hou s Renal clearance in rheumatoid ar hr tis RA) pa ients taking hydroxychloroquine sulfate for at least six mon hs seemed to be sim lar to hat of he single dose tudies in volunteers suggesting hat no change occurs w th ch onic dosing Range for enal clea ance of unchanged d ug was app oximately 16 to 30% and d d not cor elate w th creatinine clea ance therefore a dosage adjustment is not required for patients w th enal impai ment In RA patients there was la ge variabi ity as to he f action of the dose absorbed i e 30 to 100%) and mean hydroxychloroquine levels were signi ican ly higher in patients wi h less disease ac iv ty Ce lular levels of pa ients on da ly hydroxychloroquine have been shown to be higher in mononuclear cells han polymorphonuclear leucocytes

Microbiology Malaria

Mechanism of ac ion

The precise mechanism by which h d oxychloroquine exhib ts activity against *Plasmodium* is not known Hydroxychloroquine ike chloroquine is a weak base and may e ert its e fect by concent ating in the ac d esicles of he paras te and by inh bi ing polymerization of heme It can also inh bit ce tain enzymes by its inte action w th DNA

Activity in vit o and in C inical Infections

Hyd oxychloroquine is active again t he ery hrocytic forms of chloroquine sens tive strains of *Plasmodium falcipa um Plasmodium malariae Plasmodium ovale* and *Plasmodium vivax* Hyd oxychloroquine is not active against the gametocytes and exoe ythrocy ic forms including the hypnozo te stage (*P vivax* and *P ovale*) of the *Plasmodium* paras tes

Drug Resistance

P falciparum strains exhib ting educed suscept bi ity to chloroquine also show educed suscept bi ity to hydroxychloroquine

Resistance of *Plasmodium* paras tes to chloroquine is w desp ead (see **NDICATIONS AND USAGE Malaria**)

Patients in whom chloroquine or hyd oxychlo oquine have fa led to pre ent or cure c inical mala ia or paras temia or pa ients who acquired malaria in a geog aphic a ea where chloroquine resistance is known to occur hou d be t eated w th ano her form of an imalarial therapy (see **INDICATIONS AND USAGE Malaria** and **WARNINGS**)

Rheumatoid Arthri is and Systemic Lupus Erythematosus

Mechanism of ac ion

The mechanisms underlying the anti inflammatory and immunomodulatory e fects of hydroxychlo oquine su fate are unknown

IND CATIONS AND USAGE

Malaria

Hyd oxychloroquine sulfate is indicated for the t eatment of uncomplicated malaria due to *P falciparum P malariae P ovale* and *P vivax*

Hyd oxychlo oquine sulfate is indicated for the prophylaxis of malaria in geog aphic areas where chlo oquine resistance is not reported

Lim tations of Use in Malaria

- Hydroxychloroquine sulfate is not recommended for he t eatment of complicated malaria
- Hydroxychloroquine sulfate is not e fective against chloroquine or hydroxychloroquine resistant strains of *Plasmodium* species (see **CLINICAL PHARMACOLOGY Microbiology**) Hydroxychloroquine su fate is not recommended for the t eatment of malaria acquired in geographic a eas where chloroquine esistance occu s or when he *Plasmodium* species has not been dent fied
- Hydroxy hlor quine su fate is not recommended for mala ia prophylaxis in geographic a eas where chlo oquine resistance occu s
- Hydroxychlo oquine su fate does not prevent relapses of *P vivax* or *P ovale* because t is not acti e against he hypnozo te forms of these paras tes For radical cure of *P vivax* and *P ovale* infections concom tant he apy wi h an 8 aminoquino ine compound is necessary (see **CL N CAL PHARMACOLOGY Microbiology**)

P ior to prescr bing hydroxychloroquine u fate for he t eatment or prophylaxis of malaria consult the Centers for Disease Cont ol and P evention (CDC) Mala ia webs te (http //www cdc gov/mala ia)

Lupus Erythematosus

Hyd oxychloroquine su fate is indicated for the t eatment of ch onic disco d lupus ery hematosus and systemic lupus erythematosus in adults

Rheumatoid Arthri is

Hyd oxychloroquine sulfate is indicated for the treatment of acute and chronic rheumato d ar hri is in adu ts

CONTRAINDICAT ONS

Use of hydroxychloroquine su fate is cont aindicated in pa ients w th known hypersensi iv ty to 4 aminoquino ine compounds

WARNINGS

Resistant Strains of Malaria

Hyd oxychloroquine su fate is not effective against chloroquine resistant strains of *P falcipa um* (see **CLINICAL PHARMACOLOGY Mic obiology**)

Ocular

Ir evers ble retinal damage has been ob e ved in some pa ients who had received hydroxychloroquine sulfate Sign ficant risk factors for retinal damage include daily doses of hydroxychlo oquine su fate greater han 6 5 mg kg 5 mg/kg base) of actual body weight du ations of use greater than five years subnormal glome ular f lt ation use of some con omitant d ug products such as tamox fen citrate and concurrent macular disease

A base ine ocular examination is recommended w thin he first year of starting hydroxychlo oquine sulfate The base ine exam shou d include best corrected distance visual acuity (BCVA) an automated hreshold visual ie d (VF) of the central 10 degrees (w th etesting if an abnorma ity is noted) and spectral domain ocular cohe ence tomog aphy (SD OCT)

For indiv duals wi h sign ficant isk facto s (da ly dose of hyd oxychloroquine sulfate greater than 5 mg/kg base of actual body weight subnormal glome ular i t a ion use of tamoxifen cit ate or concurrent macular disease) mon toring should include annual examina ions which include BCVA VF and SD OCT For indiv duals wi hout signi icant isk factors annual exams can usua ly be defe red unt l five years of treatment

In individuals of Asian descent retinal toxicity may irst be no iced outs de the macula In pa ients of Asian descent it is recommended hat isual field testing be pe formed in the central 24 deg ees instead of the central 10 degrees

It is ecommended hat hyd oxychloroquine be discontinued if ocular toxic ty is suspected and he patient should be closely obse ved given that re inal changes (and vi ual disturbances) may progress even after cessation of therapy

Ca diac Effects Including Cardiomyopa hy and QT Prolonga ion

Postma keting cases of ife th eatening and fatal cardiomyopathy have been repo ted wi h use of hydroxychloroquine sulfate as we l as wi h use of chloroquine Patients may present w th at ioventricular block pulmonary hypertension sick sinus syndrome or w th cardiac complications ECG findings may include at ioventricular right or left bundle b anch block Signs or symptoms of cardiac compromise have appea ed during acute and h onic t eatment C inical mon to ing for signs and symptoms of ca diomyopa hy is advised including use of appropriate diagnostic tools such as ECG to monitor patients for cardiomyopathy during hydroxy hloroquine su fate the apy Ch onic toxic ty hou d be cons dered when conduc ion disorders (bundle b anch block/atrio ventricular hea t block) or biventricular hypert ophy are diagnosed If cardiotoxicity is u pected p ompt discon inuation of hydroxychloroquine su fate may p event l fe threatening complications

Hyd oxychloroquine u fate prolongs he QT inter al Ventricular arrhythmias and *torsades de pointes* have been reported in pa ients taking hyd oxychloroquine u fate (see **OVERDOSAGE**) The efore hydroxychloroquine su fate should not be administe ed w th o her drugs that have the potential to p olong he QT interval (see **DRUG INTERACT ONS**)

Worsening of Psoriasis and Porphy ia

Use of hydroxychloroquine sulfate in patients w th pso iasis may precip tate a evere attack of psoriasis When used in pa ients w th po phy ia the cond tion may be exacerbated The prepa ation shou d not be used in he e condi ions unless in the judgment of he ph sician the benefit to he patient outweighs he possible haza d

Proximal Myopathy and Neuropathy

Skeletal muscle myopathy or neuropathy leading to p ogressive weakness and atrophy of proximal muscle groups dep e sed tendon eflexes and abnormal nerve conduc ion have been reported Muscle and nerve biopsies have been associated with cu vi inear bodies and muscle fiber atrophy wi h vacuolar changes Assess muscle st eng h and deep tendon e lexes periodically in pa ients on long term the apy w th hyd oxychloroquine sulfate

Neuropsychiatric Events Including Suic da ity

Suicidal behavior has been rarely epo ted in pa ients t eated with hyd oxychloroquine sulfate

Hypoglycemia

H d oxychloroquine su fate has been shown to cause severe hypoglycemia including loss of cons iousness hat could be l fe threatening in patients t eated w th or w thout an idiabetic medica ions (see **DRUG INTERACT ONS** and **ADVERSE REACT ONS**) Patients treated wi h hydrox chloroquine su fate shou d be warned about the risk of hypoglycemia and he as ociated c inical signs and ymptoms Patients presen ing w th clinical symptoms suggestive of hypoglycemia during treatment w th hyd oxychloroquine sulfate shou d have heir blood glucose checked and t eatment eviewed as necessa y

PRECAUTIONS

General

Use w th caution in patients w th gastrointes inal neurological or blood disorders and in those w th a sens tivity to quinine

Hepatic Renal Disease

An imalarial compounds shou d be used wi h caution in pa ients w th hepatic di ease or alcoholism or in conjunction w th known hepatotoxic d ugs A educ ion in dosage may be necessary in pa ients w th hepa ic or renal disease as well as in ho e taking medicines known to a fect these o gans

Hematologic Effects/Labo atory Tests

An imala ial compounds shou d be used wi h caution in patients w th hepatic disease or alcoholism or in conjunction w th known hepatotoxic d ugs Periodic blood ce l counts should be perfo med f patients are given prolonged the apy f any se ere blood diso der such as aplastic anemia ag anulocytosis leukopenia or th ombocytopenia appea s which is not a tr butable to he di ease under t eatment consider discontinuation of hydroxychloroquine su fate

H droxy hlo oquine su fate hould be admini ter d wi h aution in patients having glucose 6 phosphate dehydrogena e (G 6 PD) de iciency

Dermatologic E fects

De matologic eactions to hydrox chlo oquine ulfate may occur and ther fore proper care shou d be exe cised when t is administe ed to any patient receiving a drug w th a sign ficant tendency to produce dermat tis

Drug Interactions

Digoxin Concom tant hydro ychlo oquine sulfate and digo in therapy may esult in increa ed serum digoxin le els serum digoxin levels should be closely mon to ed in patients receiving combined herapy

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Insulin or Antidiabe ic D ugs As hyd oxychloroquine su fate may enhance he effects of a hypoglycemic treatment a dec ease in doses of insulin or ant diabetic drugs may be required

Drugs That Prolong QT Interval and Other Arrhy hmogenic Drugs Hyd oxychlo oquine sulfate prolongs the QT interval and shou d not be administe ed w th other drugs hat ha e the potential to induce ca diac a rhythmias Also there may be an increased risk of inducing entricular arrhy hmias f hyd oxychlo oquine su fate is used concom tantly wi h o her a rhythmogenic d ugs

Mefloquine and Other Drugs Known to Lower he Convulsive Threshold Hydroxychlo oquine sulfate can lower the convulsive thresho d Co administ ation of hydroxychlo oquine sulfate with other an imalarials known to lower the convulsion hreshold (e g mefloquine) may increase he risk of convulsions

Antiepileptics The activity of an iep leptic d ugs might be impaired f co administered w th hyd oxychloroquine sulfate

Methotrexate Combined use of me hotrexate with hyd oxychloroquine su fate has not been studied and may increase he inc dence of adverse e fects

Cyclosporin An increased plasma yclospo in level was r p rted when cyclosporin and hydroxychloroquine su fate were co administe ed

The following interactions have been obse ved on treatment wi h the structura ly related substance chloroquine phosphate and therefore cannot be ruled out for hydroxychloroquine

P aziquantel Chloroquine has been repo ted to educe he bioavailabi ity of praziquantel

Antacids and Kao in Antacids and kaolin can educe ab o ption of chloroquine an interval of at least 4 hours between intake of these agents and chlo oquine should be observed

Cimetidine Cimet dine can inhibit the metabolism of chloroquine increasing ts plasma level Concom tant use of cime idine shou d be avo ded

Ampicil in In a study of heal hy voluntee s chloroquine signi ican ly reduced the bioavailabi ity of ampic l in

Information for Patients

Patients should be info med of the early signs and symptoms of toxic ty such as ra h or visual changes Patients must see their physicians promp ly in case of he appea ance of the e or of any unusual e fects Periodic laborato y tests may be ecomm nded in some pa ients Patients shou d be fully info med of the potential risks of the use of hydroxychloroquine su fate especia ly in p egnan y and in chi dren

Carcinogenesis Mutagenesis Impairment of Ferti ity

Long term studies in animals have not been conducted to evaluate the ca cinogenic potential of hyd o ychloroquine sulfate

The mutagenic poten ial of hydroxychlo oquine was not evaluated However chloroquine has been shown to be a catal tic inhib tor of DNA epair enzymes (topoisomerase I) and to p oduce weak genotoxic e fects through his mode of action

Pregnancy

Teratogenic Effects

Human p egnancies resu ting in live bi ths have been reported in he l terature and no increase in the rate of bir h defects has been demonst ated Embr onic dea hs and ma formations of anoph halmia and microphthalmia in the offspring have been reported when p egnant rats received la ge doses of chlo oquine

Nursing Mothers

Cau ion should be exe cised when administe ing hydroxychloroquine sulfate to nursing women t has been demonstrated that hydroxychloroquine administe ed to nu sing women is excreted in human mi k and it is known hat infants are e tremely sensi i e to he toxic e fects of 4 aminoquino ines

Pediatric Use

Safety and efficacy have not been estab ished in the chronic use of hydroxychloroquine su fate for ystemic lupus e ythematosus and juven le idiopa hic a thr tis in ch ldren Chi dren a e especia ly sen itive to the 4 aminoquinoline compounds Most reported fata i ies followed he accidental inges ion of chlo oquine sometimes in sma l doses 0 75 g or 1 g in one 3 year old chi d) Pa ients should be st ongly warned to keep hese drugs out of he reach of chi dren (see **OVERDOSAGE**)

Geriatric Use

C inical studies of hydroxychlo oquine su fate d d not include sufficient numbers of subjects aged 65 and over to dete mine whether they respond d ffe en ly f om younger subjects However this drug is known to be substantially exc eted by the k dney and the risk of toxic eac ions to his d ug may be g eater in pa ients w th impai ed renal function Because elderly patients a e more l kely to have decreased renal func ion care should be taken in dose selec ion and it may be useful to monitor enal function

ADVERSE REACTIONS

The fo lowing adverse reactions have been dent fied during post approval use of hydroxychloroquine su fate or other 4 aminoqunoline compounds Because hese reac ions are reported oluntar ly from a popula ion of uncertain size t is not always possible to re iably estimate their frequency or estab ish a causal elationship to d ug exposu e

Blood and lymphatic system disorders Bone ma row failure anemia aplas ic anemia agranulocytosis leukopenia and hrombocytopenia Hemolysis reported in indiv duals with glucose 6 phosphate dehydrogenase G 6 PD) deficiency

Cardiac disorders Ca diomyopa hy which may result in cardiac failure and in some ca es a fatal outcome (ee **WARNINGS** and **OVERDOSAGE**) Hydroxychloroquine su fate prolongs the QT inte val Ventricular ar hythmias and *to sade de pointes* have been reported in patients taking hyd oxychloroquine sulfate (ee **OVERDOSAGE** and **DRUG INTERACT ONS**)

Ear and labyrin h disorders Vertigo tinn tus nystagmus nerve deafness deafness

Eye disorders Ir eversible re inopathy wi h re inal pigmentation changes (bull's eye appearance) visual ie d defects (paracentral scotomas) and visual disturbances (visual acu ty) maculopathies (macular degeneration) decreased dark adaptation color vision abno mal ties co neal changes (edema and opac ties) including corneal depos tion of drug w th or wi hout accompanying symptoms (halo around ights photophobia blur ed vision)

Gast ointestinal diso ders Nausea vom ting diar hea and abdominal pain

General disorders and administra ion s te conditions Fa igue

Hepatobi iary diso de s Liver func ion tests abnormal hepatic failure acute

Immune system disorders U ticaria angioedema bronchospasm

Metabolism and nutri ion disorders Decreased appet te hypoglycemia po phy ia weight decreased

Musculoskeletal and connec ive tissue disorders Sensorimotor disorder keletal muscle myopa hy or neuromyopathy leading to progressive weakness and atrophy of p oximal muscle groups dep ession of tendon re lexes and abnormal ne ve conduction

Nervous system disorders Headache dizziness seizu e ataxia and e trapyramidal disorders such as dystonia dyskinesia and tremor have been reported w th his class of drugs

Psychiatric disorders Affect/emo ional labi ity nervousness ir itab l ty nightma es ps chosis suic dal behavior

Skin and subcutaneous tissue disorders Rash prur tus pigmenta ion diso ders in skin and mucous memb anes hair color changes alopecia De mat tis bullous e uptions including erythema mu tiforme Stevens Johnson syndrome and toxic ep dermal nec olysis drug eaction w th eosinophi ia and systemic symptoms DRESS synd ome) photosens tivity dermati is exfoliative acute genera ized exan hematous pustulosis (AGEP) AGEP has to be dis inguished from psoriasis al hough hyd oxychloroquine sulfate may precipitate a tacks of psoriasis t may be associated w th py e ia and h pe leukocytosis

To report SUSPECTED ADVERSE REACTIONS contact Sandoz Inc at 1 800 525 8747 or FDA at 1 800 FDA 1088 or www fda gov/medwatch

OVERDOSAGE

The 4 aminoquinoline compounds a e very rap dly and completely abso bed after inges ion and in accidental overdosage or arely w th lower doses in hyper ens tive pa ients toxic symptoms may occur w thin 30 minutes The symptoms of o e dosage may include headache drowsiness visual disturbances cardiovascular collapse convulsions hypokalemia rhythm and conduction disorders including QT p olongation *to sades de pointes* ventricular tachycardia and vent icular fib i la ion followed by sudden poten ia ly fatal respi atory and cardiac ar est Treatment is symptoma ic and must be p ompt Immediate gastric lavage unt l the stomach is completely emp ied is indicated A ter lavage ac ivated charcoal is introduced by the stomach tube w thin 30 minutes of ingestion of the drug may inhib t further intes inal absorp ion To be e fective the dose of ac ivated cha coal should be at least five times the estimated dose of hyd oxychloroquine ingested

Cons deration should be given to administering diazepam pa entera ly since studies suggest that t may be beneficial in reversing chlo oquine and hydroxychloroquine cardioto ic ty

Respirato y support and shock management should be inst tuted as necessary

Exchange transfusions are used to educe the level of 4 aminoquino ine drug in the blood

A pa ient who survives he acute phase and is asymptomatic shou d be closely obse ved for at least six hours Flu ds may be forced and suf icient ammonium chlo ide (8 g da ly in div ded doses for adu ts) may be administered for a few days to ac d fy the urine This w ll promote u inary exc etion in cases of both overdosage and sensitiv ty However caution must be exercised in pa ients with impaired renal function and/or metabo ic acidosis

DOSAGE AND ADM N STRATION

One tablet of 200 mg of hydroxychlo oquine su fate is equivalent to 155 mg base

Take hydroxychlo oquine su fate w th a meal or a glass of mi k

Malaria

P ophylaxis

Adu ts 400 mg 310 mg base) once weekly on the same day of each week starting 2 weeks prior to exposure and continued for 4 weeks after leaving he endemic area

Weight based dosing in adults and pediat ic pa ients 6 5 mg kg (5 mg/kg base) not to exceed 400 mg 310 mg base) once weekly on the same day of he week sta ting 2 weeks prior to exposu e and continued for 4 weeks after leaving the endemic area

Treatment of Uncomp icated Malaria

Adu ts 800 mg 620 mg base) fo lowed by 400 mg (310 mg base) at 6 hours 24 hou s and 48 hou s a ter the in tial do e (total 2000 mg hydroxychloroquine sulfate or 1550 mg base)

Weight based dosage in adu ts and pediatric patients 13 mg/kg (10 mg/kg base) not to exceed 800 mg 620 mg base) followed by 6 5 mg/kg 5 mg kg base) not to exceed 400 mg 310 mg base) at 6 hou s 24 hou s and 48 hours after the in tial dose Hyd oxychloroquine sulfate f lm coated tablets cannot be div ded ther fore they shou d not be used to treat pa ients who weigh less han 31 kg

For adical cure of *P vivax* and *P malariae* infec ions concom tant therapy wi h an 8 aminoquino ine compound is necessa y

Lupus Erythematosus

The recommended adu t dosage is 200 to 400 mg (155 to 310 mg base) da ly administered as a single daily dose or in two div ded doses Doses above 400 mg a day are not ecommended

The inc dence of retinopathy has been reported to be higher when this maintenance dose is exceeded

Rheumatoid Arthri is

The action of hydroxychloroquine is cumulative and may require weeks to mon hs to achieve the maximum the apeu ic e fect (ee **CL N CAL PHARMACOLOGY**)

Ini ial adult dosage 400 mg to 600 mg (310 to 465 mg base) da ly administered as a single da ly dose or in two div ded doses In a small pe centage of pa ients side effects may require tempora y reduction of the in tial dosage

Maintenance adu t dosage When a good response is obtained the dosage may be reduced by 50 percent and con inued at a maintenance level of 200 mg to 400 mg 155 to 310 mg base) da ly administered as a single da ly dose or in two div ded doses

Do not exceed 600 mg or 6 5 mg kg 5 mg/kg base) per day whichever is lower as the inc dence of retinopathy has been reported to be higher when his maintenance dose is exceeded

Co ticostero ds and salicylates may be used in conjunc ion with hyd oxychloroquine sulfate and they can generally be dec eased gradua ly in dosage or e iminated a ter a maintenance dose of hyd oxychloroquine sulfate has been achieved

HOW SUPPLIED

Hyd oxychloroquine su fate tablets USP for oral administ ation are ava lable as

200 mg Round o f white tablets scored and debossed GG 260 on one side and plain on the reverse s de f lm coated wh te and supp ied as

NDC 0781 1407 97 bo tles of 100
NDC 0781 1407 52 bo tles of 500
NDC 0781 1407 88 bo tles of 1000

Each tablet contains 200 mg hydroxychloroquine su fate (equivalent to 155 mg base)

Store at 20° 25°C (68° 77°F) (see USP Contro led Room Temperature)

Dispense in a tight ight resistant container as defined in the USP/NF
Keep out of the each of ch ld en

Rev MAY 2017
7456
Sandoz Inc
P inceton NJ 08540

(b) (4)

Sandoz Inc 100 Col ege Road West Princeton NJ 08540	**Description** HYDROXYCHLORAQUINE TABLETS USP Leaf et (b) (4)
	Component # 7456
	Rev Date MAY 2017
	Dimensions 25 W x 2 25 H **Drawing #** 19x2 25" 1" o d Broomfie d Pl Tmp pdf
SANDOZ	**Font Family** Helvetica Neue LT Std **S ze** 6 pt

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