APPLICATION NUMBER:
75417

DRAFT FINAL PRINTED LABELING
CLOZAPINE TABLETS
25 mg and 100 mg

DESCRIPTION
Clozapine is a piperazine compound, very slightly soluble in water.

It is also available as a 25 mg and 100 mg tablet containing 25 mg and 100 mg of clozapine in an equivalent amount of diphenhydramine hydrochloride.

CLOZAPINE TABLETS
In a controlled study comparing 25 mg and 100 mg of clozapine in adult patients suffering from manic depressive illness, the occurrence of anticholinergic side effects was not significantly different between the two dosage levels.

CLINICAL PHARMACOLOGY:
Clozapine is a potent antipsychotic drug that has been shown to be effective in the treatment of schizophrenia.

Clozapine is absorbed quickly and competes with other antipsychotics for dopamine receptors, producing atypical neuroleptic effects.

Clozapine is metabolized by the liver and the metabolites are excreted in the urine.

CLOZAPINE TABLETS
Clozapine is a potent antipsychotic drug that has been shown to be effective in the treatment of schizophrenia.

It is effective in patients with a high risk of suicidal behavior or those who have failed to respond to other antipsychotic medications.

Clozapine increases the concentration of dopamine in the brain and reduces the levels of serotonin and noradrenaline.

CLOZAPINE TABLETS
Clozapine is a potent antipsychotic drug that has been shown to be effective in the treatment of schizophrenia.

It is effective in patients with a high risk of suicidal behavior or those who have failed to respond to other antipsychotic medications.

Clozapine increases the concentration of dopamine in the brain and reduces the levels of serotonin and noradrenaline.

CLOZAPINE TABLETS
Clozapine is a potent antipsychotic drug that has been shown to be effective in the treatment of schizophrenia.

It is effective in patients with a high risk of suicidal behavior or those who have failed to respond to other antipsychotic medications.

Clozapine increases the concentration of dopamine in the brain and reduces the levels of serotonin and noradrenaline.

CLOZAPINE TABLETS
Clozapine is a potent antipsychotic drug that has been shown to be effective in the treatment of schizophrenia.

It is effective in patients with a high risk of suicidal behavior or those who have failed to respond to other antipsychotic medications.

Clozapine increases the concentration of dopamine in the brain and reduces the levels of serotonin and noradrenaline.
Detective hypoglycemia with unexplained chills can occur with chronic treatment with insulin. This may represent a significant risk in some patients. Approximately 1% of patients experience serum hyperglycemia with unexplained hypoglycemia. Treatment with diazoxide may decrease this risk. However, diazoxide is not without serious complications and should be used with caution.

Adverse dermatological and respiratory reactions:

- Hypersensitivity reactions with unexplained chills can occur with chronic treatment with insulin. This may represent a significant risk in some patients. Approximately 1% of patients experience serum hyperglycemia with unexplained hypoglycemia. Treatment with diazoxide may decrease this risk. However, diazoxide is not without serious complications and should be used with caution.

- Adverse reactions with unexplained chills can occur with chronic treatment with insulin. This may represent a significant risk in some patients. Approximately 1% of patients experience serum hyperglycemia with unexplained hypoglycemia. Treatment with diazoxide may decrease this risk. However, diazoxide is not without serious complications and should be used with caution.

- Adverse reactions with unexplained chills can occur with chronic treatment with insulin. This may represent a significant risk in some patients. Approximately 1% of patients experience serum hyperglycemia with unexplained hypoglycemia. Treatment with diazoxide may decrease this risk. However, diazoxide is not without serious complications and should be used with caution.

- Adverse reactions with unexplained chills can occur with chronic treatment with insulin. This may represent a significant risk in some patients. Approximately 1% of patients experience serum hyperglycemia with unexplained hypoglycemia. Treatment with diazoxide may decrease this risk. However, diazoxide is not without serious complications and should be used with caution.
Hepatitis has been reported in 1/20 patients with normal and non-normal function liver function tests.

In patients who develop jaundice, clinical and biochemical manifestations include fever, anorexia, nausea, vomiting, loss of appetite, abdominal pain, darkening of urine, and lightening of stools. Clinical signs of portal hypertension and extrahepatic manifestations, such as splenomegaly, ascites, and leg edema, may also occur. In some patients, a retro-renal caput medusae (spider angioma) can be observed on the skin of the abdomen or chest, and this is associated with portal hypertension.

Acute Hepatitis

Acute hepatitis is a condition characterized by inflammation of the liver, leading to liver dysfunction and elevated liver enzymes. The symptoms of acute hepatitis include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Persistent Hepatitis

Persistent hepatitis is a condition characterized by persistent inflammation of the liver, leading to liver dysfunction and elevated liver enzymes. The symptoms of persistent hepatitis include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Chronic Hepatitis

Chronic hepatitis is a condition characterized by persistent inflammation of the liver, leading to liver dysfunction and elevated liver enzymes. The symptoms of chronic hepatitis include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis A

Hepatitis A is a viral infection of the liver caused by the hepatitis A virus (HAV). It is spread through the ingestion of contaminated food or water. The symptoms of hepatitis A include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis B

Hepatitis B is a viral infection of the liver caused by the hepatitis B virus (HBV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis B include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis C

Hepatitis C is a viral infection of the liver caused by the hepatitis C virus (HCV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis C include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis D

Hepatitis D is a viral infection of the liver caused by the hepatitis D virus (HDV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis D include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis E

Hepatitis E is a viral infection of the liver caused by the hepatitis E virus (HEV). It is spread through the ingestion of contaminated food or water. The symptoms of hepatitis E include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis G

Hepatitis G is a viral infection of the liver caused by the hepatitis G virus (HGV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis G include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis F

Hepatitis F is a viral infection of the liver caused by the hepatitis F virus (HFV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis F include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis I

Hepatitis I is a viral infection of the liver caused by the hepatitis I virus (HIV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis I include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis J

Hepatitis J is a viral infection of the liver caused by the hepatitis J virus (HJV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis J include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis K

Hepatitis K is a viral infection of the liver caused by the hepatitis K virus (HKV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis K include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis L

Hepatitis L is a viral infection of the liver caused by the hepatitis L virus (HLV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis L include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis M

Hepatitis M is a viral infection of the liver caused by the hepatitis M virus (HMV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis M include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis N

Hepatitis N is a viral infection of the liver caused by the hepatitis N virus (HNV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis N include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis O

Hepatitis O is a viral infection of the liver caused by the hepatitis O virus (HOV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis O include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis P

Hepatitis P is a viral infection of the liver caused by the hepatitis P virus (HPV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis P include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis Q

Hepatitis Q is a viral infection of the liver caused by the hepatitis Q virus (HQV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis Q include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis R

Hepatitis R is a viral infection of the liver caused by the hepatitis R virus (HRV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis R include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis S

Hepatitis S is a viral infection of the liver caused by the hepatitis S virus (HSV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis S include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis T

Hepatitis T is a viral infection of the liver caused by the hepatitis T virus (HTV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis T include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis U

Hepatitis U is a viral infection of the liver caused by the hepatitis U virus (HU). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis U include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis V

Hepatitis V is a viral infection of the liver caused by the hepatitis V virus (HV). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis V include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis W

Hepatitis W is a viral infection of the liver caused by the hepatitis W virus (HW). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis W include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis X

Hepatitis X is a viral infection of the liver caused by the hepatitis X virus (HX). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis X include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis Y

Hepatitis Y is a viral infection of the liver caused by the hepatitis Y virus (HY). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis Y include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.

Hepatitis Z

Hepatitis Z is a viral infection of the liver caused by the hepatitis Z virus (HZ). It is spread through the exchange of blood, semen, or other bodily fluids. The symptoms of hepatitis Z include fatigue, anorexia, nausea, vomiting, abdominal pain, jaundice, and dark urine.
Each tablet contains:

CLOZAPINE 25 mg

100 TABLETS

CLOZAPINE 100 mg

500 TABLETS

CLOZAPINE 100 mg

100 TABLETS