

**Hansepran 50mg****CLOFAZIMINE 50 MG**

HANSEPRAN 50MG contains Clofazimine which belongs to the group of medicines called Antimycobacterial agents. It is used to treat lepromatous leprosy (including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum) in combination with other anti-leprosy drugs.

Leprosy is a chronic and contagious infection caused by mycobacterium leprae which affects the skin, nerves outside the brain and spinal cord including upper respiratory tract's mucosa, and eyes. It is generally characterized by symptoms such as discoloured skin patches with loss of sensations, numbness or tingling sensation (in hands, feet, arms and legs), painless wounds/burns (typically on hands and feet) and muscle weakness.

HANSEPRAN 50MG is not recommended for use if you have a personal or family history of heart disease such as congenital long QT syndrome (a type of hereditary heart disease). It should be used with caution in patients with frequent stomach pain, continuous vomiting or diarrhoea, hepatitis B or C (liver infection), liver, kidney or other heart problems. HANSEPRAN 50MG should be used with caution in pregnant women and it is not recommended for use in breastfeeding women.

HANSEPRAN 50MG is recommended for use in children and adolescents (aged 10 to 14 years) and it should be used with caution in children (aged below 10 years). Also, it should be used with caution in elderly patients (aged 65 years and above). Consult your doctor before taking HANSEPRAN 50MG. The common side effects associated with the use of HANSEPRAN 50MG are reversible reddish dark-brown discolouration of skin, hair and eyes, discolouration of body fluids (such as sweat, saliva, tears, urine, and stools), abdominal pain, diarrhoea, nausea, vomiting and dryness of skin. Consult your doctor if any of the symptom worsens.

**USES OF HANSEPRAN 50MG**

Used in combination with other anti-leprosy drugs to treat:

- lepromatous leprosy
- dapsone-resistant lepromatous leprosy
- lepromatous leprosy complicated by erythema nodosum leprosum

HANSEPRAN 50MG induces membrane dysfunction in the bacterial cell which also works by blocking the production of certain cells (responsible for causing inflammation) in the body that results in destruction of bacterial cell and prevention of inflammatory reaction in the body thus helps to treat lepromatous leprosy and its associated symptoms.

Take HANSEPRAN 50MG as advised by your physician. Swallow the medicine with a glass of water. Do not crush or chew the medicine. Your doctor will decide the correct dose and duration for you depending upon your age, body weight and disease condition.

## **SIDE EFFECTS OF HANSEPRAN 50MG**

### **COMMON**

- discolouration of lining of the eyelids and body fluids such as sweat, sputum, saliva, tears, urine and stools
- reversible reddish/pink to dark brown, black discolouration of the skin, hair and eyes
- upper abdominal pain
- diarrhoea
- nausea
- vomiting
- food intolerance
- scaling and dryness of skin
- rashes
- itching
- pigmentation in eyes
- dryness, burning, itching or irritation in eyes
- high blood sugar levels
- signs of elevated erythrocyte sedimentation rate (ESR) such as increased frequency of infections
- disturbed eyesight
- weight loss

### **UNCOMMON**

- headache
- loss of appetite
- increased skin sensitivity to sunlight
- skin reactions such as acneiform eruptions (condition marked by acne like bumps eruption)
- tiredness
- swollen lymph nodes
- dizziness
- constipation
- jaundice (yellowish discoloration of the eyes and skin)
- fever
- erythroderma (inflammation of skin surface)
- monilial cheilosis (fungal infection at the angles of the mouth)
- anorexia (an eating disorder causing weight gain or weight loss)
- eosinophilic enteritis (rare inflammatory disorder of intestinal wall)
- maculopathy (an eye disorder)
- drowsiness
- giddiness
- neuralgia (pain at path of the nerve)
- taste disturbance
- splenic infarction (impaired blood supply to spleen)
- thromboembolism (blood clots causing blockage in blood vessels)
- anaemia (reduced blood cell count)
- cystitis (inflammation of urinary bladder)
- bone pain
- oedema (swelling in hands and feet caused by water retention)
- signs of vascular pain such as heaviness/pain in the vascular disease/injury area

## **RARE**

Stop taking HANSEPRAN 50MG and contact your doctor if you experience any of the following side effects:

- skin rash
- signs of liver damage such as severe nausea, vomiting, abdominal pain, bloody or black tarry stools and yellow eyes or skin
- signs of heart rhythm disturbances such as irregular heartbeat, dizziness, fainting, shortness of breath and severe tiredness
- upper stomach pain accompanied by fever, chills, chest, left shoulder pain, nausea and vomiting
- blurred or cloudy vision
- bowel obstruction
- signs of bleeding in stomach and intestine such as black stools
- signs of hepatitis such as feeling unwell, nausea, vomiting, a loss of appetite, and fever
- serious skin reactions such as flaking and peeling of skin
- severe dryness, burning, itching, or irritation in eyes
- severe eyesight problems
- severe skin rash and itchiness
- extreme weight loss
- depression due to skin discoloration

### **Diarrhoea:**

Drink lot of fluids, such as water to keep yourself hydrated. Try to avoid taking any medicine on your own to treat diarrhoea and consult your doctor if the symptom gets worse.

### **Nausea and vomiting:**

Try to take HANSEPRAN 50MG with or just after a meal or a snack. Stick to simple meals. Avoid eating oily, fried or spicy foods. Consult your doctor if the symptom gets worse.

### **Itchy Skin:**

Try to pat or tap your skin instead of scratching it. Hold a damp towel to cool your skin. Wear loose clothing and avoid tight clothes, or clothes made from wool or synthetic fabrics. Avoid using perfumed soaps, deodorants or moisturizers and use a skin softener regularly. Consult your doctor if the symptom gets worse.

### **Headache:**

Apply hot or cold-water bag on your head. Try taking rest in a quiet and dark room. Apply pain relieving balm on your forehead if necessary. Drink sufficient amount of fluids and avoid skipping meals. Consult your doctor if the symptom does not improve.

### **Constipation:**

Take fiber rich foods in your diet such as fresh fruits, vegetables and whole grain cereals and drink plenty of fluids. Exercise more regularly and stay active. Consult your doctor if the symptom gets worse.

## **WARNING & PRECAUTIONS**

### **PREGNANCY**

HANSEPRAN 50MG should be used with caution in pregnant women and in women planning for pregnancy only if it is considered clearly necessary. Consult your doctor before taking HANSEPRAN 50MG.

### **BREASTFEEDING**

HANSEPRAN 50MG is not recommended for use in breastfeeding women as it may pass through milk. Consult your doctor before taking HANSEPRAN 50MG.

### **DRIVING AND USING MACHINES**

Do not drive or operate any machines while taking HANSEPRAN 50MG as this medicine can cause dizziness, tiredness, headache and/or eyesight problems. Consult your doctor before taking HANSEPRAN 50MG.

### **KIDNEY**

HANSEPRAN 50MG should be used with caution in patients with kidney problems. Consult your doctor before taking HANSEPRAN 50MG.

### **LIVER**

HANSEPRAN 50MG should be used with caution in patients with liver problems such as hepatitis B or C (liver infection). Consult your doctor before taking HANSEPRAN 50MG.

### **ALLERGY**

HANSEPRAN 50MG is not recommended for use if you are allergic to clofazimine, peanuts, soya, or any other ingredients of this medicine.

### **HEART DISEASE**

HANSEPRAN 50MG is not recommended for use if you have a personal or family history of heart problem such as congenital long QT syndrome (heart rhythm disorder). It should be used with caution in patients with other heart problems. Consult your doctor before taking HANSEPRAN 50MG.

### **OTHERS**

Before taking HANSEPRAN 50MG, inform your doctor if you have:

- frequent stomach pain
- continuous diarrhoea or vomiting

### **Use in Paediatrics:**

HANSEPRAN 50MG is recommended for use in children and adolescents (aged 10 to 14 years). It should be used with caution in children (aged below 10 years) after consulting the doctor who might decide the dosage based on child's age, body weight and disease condition.

### Use in Geriatrics:

HANSEPRAN 50MG should be used with caution in elderly patients (aged 65 years or above). Consult your doctor before taking HANSEPRAN 50MG.

## INTERACTIONS

### A. Drug-Drug Interactions

Before taking HANSEPRAN 50MG, inform your doctor, if you are taking any of the following medicines:

- other medicines used to treat leprosy Ex. dapsone
- medicines used to treat tuberculosis and leprosy Ex. rifampicin, isoniazid, bedaquiline and delamanid
- azithromycin, clarithromycin and fluoroquinolones such as levofloxacin (used to treat bacterial infections)
- amprenavir, delaviridine, efavirenz, etravirine, indinavir, nelfinavir, raltegravir, rilpivirine, simeprevir, maraviroc (used to treat HIV infection)
- medicines to lower blood cholesterol levels Ex. simvastatin, lovastatin
- medicines used to treat high blood pressure Ex. losartan, verapamil, diltiazem, nitrendipine, amlodipine, nifedipine, nifedipine, eplerenone, felodipine, lercanidipine
- medicines to reduce blood sugar levels Ex. pioglitazone, repaglinide, saxagliptin
- phenytoin, fosphenytoin (used to control seizures)

### Overdosage:

If you or anyone else accidentally takes too much of HANSEPRAN 50MG, consult your doctor immediately or visit the nearby hospital if you experience any unusual symptoms.

## SYNOPSIS

**Drug** : Clofazimine

**Pharmacological Category** : Antimycobacterial agent

**Therapeutic Indication** : Lepromatous leprosy

**Dosage Forms** : Capsule



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