

# **A Guide for Patients And Caregivers:**

**What You Need to Know about Leponex and the risk of Agranulocytosis**

## What You Need to Know about Clozapine and agranulocytosis:

### What is Leponex and What is it indicated for?

Leponex is a prescription medicine to treat people with schizophrenia who have not responded to other medicines. Leponex may also reduce the risk of suicidal behavior.

Leponex is indicated in treatment-resistant schizophrenic patients and in schizophrenia patients who have severe, untreatable neurological adverse reactions to other antipsychotic agents, including atypical antipsychotics. Treatment resistance is defined as a lack of satisfactory clinical improvement despite the use of adequate doses of at least two different antipsychotic agents, including an atypical antipsychotic agent, prescribed for adequate duration. Leponex is also indicated in psychotic disorders occurring during the course of Parkinson's disease, in cases where standard treatment has failed.

### What is the most serious risk information about Leponex treatment?

**Leponex can cause agranulocytosis.** Agranulocytosis is a blood disorder that occurs when a certain type of white blood cells called neutrophils are not made or not enough of them are made. This makes it harder for your body to fight infections.

Before you can start Leponex and during treatment, you must have regular blood tests to measure the number of neutrophils you have in your blood. This test is called absolute neutrophil count (ANC). If the number of neutrophils, or ANC, is too low, you may have to stop Leponex. Your doctor will decide if or when it is safe to restart Leponex.

This is not the only serious risk associated with Leponex treatment. Talk to your doctor about the other serious risks.

### What are the symptoms of agranulocytosis?

You might not have any symptoms at all. Getting your blood tested to measure the number of neutrophils is the only way to check for agranulocytosis. This helps your doctor know if you are more likely to get an infection.



#### **If you have any of these symptoms, talk to your doctor right away**

- Infection, including skin, throat, urinary tract, vaginal, pneumonia, or any other infection
- Fever or chills
- Sores or ulcers inside your mouth, gums, or on your skin
- Wounds that take a long time to heal
- Feel like you have the flu
- Pain or burning while urinating
- Unusual vaginal discharge or itching
- Abdominal pain
- Sores or pain in or around your rectal area
- Feel extremely weak or tired

## What You Need to Know about Clozapine and agranulocytosis:

### What can I do to help reduce the risk of developing agranulocytosis?



#### Three important things you can do:

1. Have your blood tested as instructed by your doctor
2. Tell your doctor about all the medicines you are taking (prescription and over-the-counter), and if you start a new medicine
3. Tell your doctor right away if you get a fever or feel sick

### What are the blood testing requirements for Leponex?

#### Get your Blood Tested

- Your doctor will give you an order to have blood tests done
- You will need to get your blood tested on the following schedule or as directed by your doctor:
  - Weekly blood tests for the first 6 months you are taking Leponex
  - Every 2 weeks for the next 6 months if your ANC stays normal
  - Every 4 weeks after the first year if your ANC stays normal

#### Monitoring Results

- If your ANC is too low, your doctor will schedule blood tests more frequently

#### No Blood, No Drug

- *Remember: You must get your blood tested before you can receive Leponex from your pharmacy! Please refer to Patient Information Leaflet for more information.*

#### You can report any problem or adverse events through:

##### **Novartis Consulting AG:**

Phone: +996112658100  
Mobile : 0508035430  
Fax: +966112658107  
Email: [adverse.events@novartis.com](mailto:adverse.events@novartis.com)

##### **Saudi Food and Drug Authority National Pharmacovigilance Center (NPC):**

Toll free phone: 8002490000  
Fax: +966112057662  
E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)  
Or by online: <https://ade.sfda.gov.sa>