A Guide for Patients **And Caregivers:**

What You Need to Know about Zapnex and the risk of Agranulocytosis

This guide approved by Saudi food and drug Authority

What You Need to Know about Zapnex and agranulocytosis:

What is Zapnex and What is it indicated for?

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

Zapnex 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. 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 Zapnex treatment?

Zapnex 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 Zapnex and during treatment, you must have regular blood tests to measure 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 Zapnex. Your doctor will decide if or when it is safe to restart Zapnex.

This is not the only serious risk associated with Zapnex 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 Zapnex 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 doctor
- Tell your doctor about all the medicines you are taking (prescription and Over-the-counter), and if you start a new medicine
- Tell your doctor right away if you get a fever or feel sick

What are the blood testing requirements for Zapnex?

	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:
Get your	- Weekly blood tests for the first 6

Blood **Tested**

taking Zapnex Every 2 weeks for the next 6 months If your ANC stays normal

months you are

Every 4 weeks after the first year if your ANC stays normal

Monitoring Results

No Blood,

No Drug

- If your ANC is too low. your doctor will schedule blood tests more frequently
- Remember: you must get your blood tested before you can receive Zapnex from your Pharmacy! Please refer to Patient Information Leaflet for more information.

You can report any problem or adverse events through:

- The National Pharmacovigilance Center (NPC)
 - Fax: +966-11-205-7662
 - Toll free phone: 8002490000
 - SFDA Call Center: 19999
 - E-mail: npc.drug@ sfda.gov.sa
 - Website: https:// ade.sfda.gov.sa/

You should also report any side effects to Aurobindo Pharma Saudi Arabia Limited, Jeddah, Pharmacovigilance department on +966 (0) 12 6688856 Ext. 107 or pv.apsal@aurobindo.com

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