



## 1.5.4. Mock-Ups and Specimens

### LEAFLET

#### PZ-1 / PZ-4 TABLETS (Pimozide Tablets BP 1 mg / 4 mg)

##### Composition:

##### PZ-1

Each uncoated tablets contains  
Pimozide BP 1 mg

##### PZ-4

Each uncoated tablets contains  
Pimozide BP 4 mg

Category: Antipsychotic drug

##### Clinical Pharmacology:

Pimozide is an orally active antipsychotic drug product which shares with other antipsychotics the ability to block dopamine receptors in the central nervous system. Although its exact mode of action has not been established, the ability of pimozide to suppress motor and phonic tics in Tourette's Disorder is thought to be a function of its dopaminergic blocking activity. However, receptor blockade is often accompanied by a series of secondary alterations in central dopamine metabolism and function which may contribute to both pimozide's therapeutic and untoward effects. In addition, pimozide, in common with other antipsychotic drugs, has various effects on other central nervous system receptor systems which are not fully characterized.

##### Metabolism and Pharmacokinetics

More than 50% of a dose of pimozide is absorbed after oral administration. Based on the pharmacokinetic and metabolic profile, pimozide appears to undergo significant first pass metabolism. Peak serum levels occur generally six to eight hours (range 4-12 hours) after dosing.

##### Indication:

Pimozide is indicated for the suppression of motor and phonic tics in patients with Tourette's Disorder who have failed to respond satisfactorily to standard treatment.

Pimozide should be reserved for use in Tourette's Disorder patients whose development and/or daily life function is severely compromised by the presence of motor and phonic tics.

##### Dosage & Administration

##### Schizophrenia,

ADULT & CHILD over 12 years, initially 2mg daily, increased according to response in steps of 2-4 mg at intervals of not less than 1 week; usual dose range 2-20 mg daily; ELDERLY half usual starting dose.

Monosymptomatic hypochromidical psychosis, paranoid psychosis, ADULT & CHILD over 12 years, initially 4mg daily, increased according to response in steps of 2-4 mg at intervals of not less than 1 week maximum 16 mg daily; ELDERLY half usual starting dose.

##### Contraindications:

• Pimozide is contraindicated in the treatment of simple tics or tics other than those associated with Tourette's Disorder.

• Pimozide should not be used in patients taking drugs that may, themselves, cause motor and phonic tics (e.g., pemoline, methylphenidate and amphetamines until such patients have been withdrawn from these drugs to determine whether or not the drugs, rather than Tourette's Disorder, are responsible for the tics.

• Because Pimozide prolongs the QT interval of the electrocardiogram it is contraindicated in patients with congenital long QT syndrome, patients with a history of cardiac arrhythmias, patients taking other drugs which prolong the QT interval of the electrocardiogram or patients with known hypokalemia or hypomagnesemia.

• Pimozide is contraindicated in patients with severe toxic central nervous system depression or comatose states from any cause.

• Pimozide is contraindicated in patients with hypersensitivity to it. As it is not known whether cross-sensitivity exists among the antipsychotics, Pimozide should be used with appropriate caution in patients who have demonstrated hypersensitivity to other antipsychotic drugs.

##### Drug Interactions

• Pimozide+amprenavir- Using pimozide together with amprenavir is not recommended. Combining these medications may significantly increase the blood levels of pimozide. High blood levels of pimozide can increase the risk of an irregular heart rhythm that may be serious and potentially life-threatening, although it is a relatively rare side effect. You may be more susceptible if you have a heart condition called congenital long QT syndrome, other cardiac diseases, conduction abnormalities, or electrolyte disturbances.

• Pimozide+azithromycin- Using azithromycin and pimozide is not recommended. Taking these drugs together can affect the rhythm of

your heart. Call your doctor if you have symptoms of irregular heartbeat, chest lightness, blurred vision or nausea.

• Pimozide+bosutinib- Using pimozide together with bosutinib is not recommended. Combining these medications can increase the risk of an irregular heart rhythm that may be serious and potentially life-threatening, although it is a relatively rare side effect. You may be more susceptible if you have a heart condition called congenital long QT syndrome, other cardiac diseases, conduction abnormalities, or electrolyte disturbances.

• Pimozide+clozapine- Using pimozide together with clozapine is not recommended. Combining these medications can increase the risk of an irregular heart rhythm that may be serious and potentially life-threatening, although it is a relatively rare side effect. You may be more susceptible if you have a heart condition called congenital long QT syndrome, other cardiac diseases, conduction abnormalities, or electrolyte disturbances.

##### Warnings and precautions

• Talk to your doctor or pharmacist before using Pimozide tablets

• If you have heart problem or anyone in your close family has died suddenly of heart problems

• If you have liver or kidney problems

• If you have epilepsy or any other problem that can cause fits (convulsions)

• If you have problems with your thyroid gland

• If you have a non-cancerous tumour of the adrenal gland (phaeochromocytoma)

• If you have a history of blood clots, or someone else in your family has (as medicines like this have been associated with formation of blood clots)

• If you exercise hard, are going somewhere very hot or don't drink enough

• You may need to be more closely monitored, and the amount of Pimozide tablets you take may have to be altered.

##### Side Effects:

Stop using Pimozide tablets and consult the doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

##### More common

• Sweating more than usual

• Urinating (passing water) at night

• Feeling dizzy

• Feeling sleepy

• Rash, hives (also known as nettle rash or urticaria), severe irritation of your skin. These may be signs of a severe allergic reaction. This only happens in a small number of people

• A serious problem called 'neuroleptic malignant syndrome'. The signs may include:

• Fast heart beat, changing blood pressure and sweating followed by fever

• Faster breathing, muscle stiffness, reduced consciousness and coma

• Raised levels of a protein in your blood (an enzyme called creatine phosphokinase)

• Your heart:

• Beats abnormally (arrhythmia)

• Flutters (fibrillates)

• Beats unusually fast (tachycardia)

An arrhythmia can cause your heart to stop beating (cardiac arrest). Unexplained deaths have occurred rarely in patients taking this type of medicine

• Jerky movements and problems such as slowness, muscle stiffness or spasm, shaking, trembling or tremors, feeling restless and stiff neck. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat, difficulty speaking or rolling of the eyes. If you get any of these effects, you may be given an additional medicine

• Low sodium levels in the blood which can cause tiredness and confusion, muscle twitching, fits or coma.

##### STORAGE:

Store under normal storage condition (15°C to 30°C).

Protect from light.

Keep all medicines out of reach of children.

##### PRESENTATION:

A Bulk pack of 30's & 240's Tablets

Manufactured in India by :

**AGOG PHARMA LTD.**



Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.