

**DEPIA®**  
**Tablets & Oral solution**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about DEPIA**

Each tablet of DEPIA 2 contains 2 mg risperidone with the following excipients: lactose monohydrate, microcrystalline cellulose, magnesium stearate, Croscarmellose sodium, butyl hydroxyl toluene and yellow quinolone.

Each tablet of DEPIA 4 contains 4 mg risperidone with the following excipients: lactose monohydrate, microcrystalline cellulose, magnesium stearate, Croscarmellose sodium, butyl hydroxyl toluene and indigo blue.

Each 5 mL of DEPIA oral solution contains 5 mg risperidone with the following excipients: tartaric acid, benzoic acid, sodium hydroxide and purified water.

DEPIA tablets and oral solution are for oral use. Risperidone is an antipsychotic agent. Its therapeutic activity is mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism.

DEPIA is indicated for:

- Acute and maintenance treatment of schizophrenia and related psychotic disorders in adults and adolescents aged 13 years of age and older
- Alone, or in combination with lithium or valproate, for the treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults, adolescents and children 10 years of age and older
- Treatment of irritability associated with autistic disorder in children 5 years of age and older and in adolescents

This medicine may be used to treat other conditions as well such as short term treatment of persistent aggression in patients with Alzheimer's dementia or in children with mental retardation.

**The way to take DEPIA**

Take DEPIA as directed by your doctor. Do not discontinue the treatment without consulting your doctor. Dosage is individualized through consideration of severity of symptoms. DEPIA can be given with or without meals.

DEPIA can be administered once or twice daily. The therapy is initiated at a low dose and then increased gradually and maintained to the most effective and well tolerated dosage.

The usual recommended dosages are:

<b>Indication</b>	<b>Initial dose</b>	<b>Titration</b>	<b>Target dose</b>	<b>Effective dose range</b>
Schizophrenia; adults	2 mg/day	1-2 mg daily	4-8 mg/day	4-16 mg/day
Schizophrenia; adolescents	0.5 mg/day	0.5-1 mg daily	3 mg/day	1-6 mg/day
Bipolar mania; adults	2-3 mg/day	1 mg daily	1-6 mg/day	1-6 mg/day
Bipolar mania; in children /	0.5 mg/day	0.5-1 mg daily	2.5 mg/day	0.5-6 mg/day

adolescents				
Irritability associated with autistic disorder	0.25 mg/day (for children less than 20 kg) 0.5 mg/day (for children weighing 20 kg and over)	0.25-0.5 mg at least 2 weeks intervals	0.5 mg/day (<20 kg) 1 mg/day (≥20 kg)	0.5-3 mg/day

DEPIA oral solution can be administered directly from the dosing cup or can be mixed with water, coffee, juice or a non-alcoholic beverage (except tea or cola) prior to administration.

#### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

#### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

#### **Contraindications**

This drug is contraindicated in patients with a known hypersensitivity to any of the components.

#### **Precautions**

- This drug must be used with caution in elderly patients, and in case of severe cardiovascular disorders, renal or hepatic impairment, history of seizure disorders, Parkinson's disease, or diabetes mellitus.
- You should be cautious when driving a car or operating machinery, until you are certain that you are not adversely affected by drowsiness or dizziness.
- It is advisable to get up slowly when rising from a lying or sitting position to avoid dizziness.
- Inform your doctor if you become pregnant or intend to become pregnant during therapy. Women should not breast feed during treatment with this medication.

#### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Avoid the use of alcohol with this drug. Caution should be used when taking this drug in combination with other centrally acting drugs.

You may require dosage adjustment or special monitoring during treatment if you are taking any of the following medicines: antihypertensive medications, levodopa, bromocriptine, clozapine, cimetidine, ranitidine, fluoxetine, paroxetine, carbamazepine, phenytoin, rifampicin or phenobarbital.

#### **Adverse reactions**

The most reported adverse reactions include: hyperglycemia, orthostatic hypotension, dizziness, tachycardia, elevation of prolactin levels, somnolence, agitation, fatigue, anxiety, headache, constipation, vision changes, dysphagia, rash, dyspepsia and weight gain.

Tardive dyskinesia (a movement disorder), Parkinsonism (rigidity, hypersalivation and tremor), Neuroleptic Malignant Syndrome (paleness, hyperpyrexia, muscle rigidity and altered mental status) and cerebrovascular events have been reported with antipsychotic drugs.

Please inform your doctor if any side effect appears or becomes bothersome.

#### **Storage**

Store below 30°C, protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

#### **Pack Presentation**

DEPIA 2, risperidone 2 mg, pack of 20 tablets

DEPIA 4, risperidone 4 mg, pack of 20 tablets

DEPIA oral solution, risperidone 1 mg/mL, bottle of 100 mL with a dosing cup

**Revision date: 08/2024**

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Marketing Authorization Holder and Manufacturer: Mediphar Laboratories - Lebanon