REVIEW / DERLEME

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Lurasidone in the Treatment of Childhood and Adolescent Psychopathology: Evidence and Emerging Perspectives

Çocukluk ve Ergenlik Dönemi Psikopatolojilerinin Tedavisinde Lurasidon: Kanıtlar ve Gelişen Perspektifler

Bedia Sultan Önal, Cansu Ölçer, Berkan Şahin, Cansu Çobanoğlu Osmanlı

Giresun University Faculty of Medicine, Department of Child and Adolescent Psychiatry, Giresun, Türkiye

ABSTRACT

Lurasidone is a commonly prescribed second-generation antipsychotic used in the treatment of schizophrenia and bipolar depression in adults. Interest in using it to treat mood and psychotic disorders in children is growing. There is a dearth of information on its safety, effectiveness, and optimal use in younger populations, despite its expanding clinical use. The effectiveness, safety, and tolerability of lurasidone in the treatment of psychiatric disorders in children and adolescents are the main topics of this review. Using search terms such as "lurasidone," "antipsychotic," "bipolar," "schizophrenia," "depression," "children," and "adolescents," a thorough literature review was carried out. PsycINFO, Google Scholar, and PubMed were among the databases that were searched. Publications were analyzed for pharmacological properties, clinical efficacy, side-effect profiles, and clinical recommendations. Lurasidone has demonstrated efficacy and safety in the treatment of schizophrenia and bipolar depression in specific pediatric age groups. Common adverse effects include somnolence, extrapyramidal symptoms, akathisia, and nausea. Compared to other antipsychotics, lurasidone appears to have a limited impact on weight gain and metabolic parameters. It is generally well tolerated, with mild withdrawal symptoms upon discontinuation. This review presents current evidence regarding lurasidone use in adolescents with schizophrenia, schizoaffective disorder, and bipolar disorder. Current evidence indicates that lurasidone is a promising treatment option for children and adolescents with schizophrenia and bipolar depression, particularly due to its favorable metabolic profile and overall tolerability. However, the available studies remain limited in number and scope. Future large-scale, well-designed randomized controlled trials are essential to confirm these findings, clarify long-term safety, and establish evidence-based clinical guidelines for the use of lurasidone in pediatric populations.

Keywords: Lurasidone, treatment, psychopathology, child and adolescent

ÖZ

Lurasidon, yetişkinlerde şizofreni ve bipolar depresyon için yaygın olarak reçete edilen ikinci nesil antipsikotiklerden biridir. Pediyatrik popülasyonlarda duygu durum ve psikotik bozukluklar için kullanımı konusundaki ilgi giderek artmaktadır. Klinik uygulamalarda kullanımı artmasına rağmen, lurasidonun daha genç popülasyonlardaki etkinliği, güvenliği ve optimal kullanımıyla ilgili veriler hala oldukça sınırlıdır. Bu inceleme, lurasidonun psikiyatrik bozuklukları olan çocuklar ve ergenlerdeki kullanımını değerlendirerek etkinliğini, güvenliğini ve tolerabilitesini kapsayan bir klinik yaklaşımı incelemeyi amaçlamaktadır. İlgili literatür üzerine kapsamlı bir inceleme yapılmış olup, arama terimleri arasında "lurasidon", "antipsikotik", "bipolar", "şizofreni", "depresyon", "çocuklar" ve "ergenler" yer almıştır. PubMed, Google Scholar ve PsycINFO veritabanlarını kullanarak bir literatür taraması gerçekleştirdik ve odak noktamız, randomize kontrollü çalışmalar, açık etiketli çalışmalar, derleme makaleleri, meta-analizler ve gözlemsel çalışmalardı. Yayınlar, lurasidonun farmakolojik özellikleri, klinik etkinliği, yan etki profilleri ve klinik uygulama önerileri açısından analiz edilmiştir. Lurasidonun belirli yaş gruplarındaki çocuklar ve ergenlerde şizofreni ve bipolar depresyon tedavisinde etkili ve güvenli olduğu gösterilmiştir. Yaygın yan etkiler arasında uyku hali, ekstrapiramidal semptomlar, akatizi ve mide bulantısı yer almaktadır. Diğer antipsikotiklerle karşılaştırıldığında, lurasidonun kilo alımı ve metabolik parametreler üzerindeki etkisinin sınırlı olduğu görülmüştür. İyi tolere edilebildiği ve ilaç sonlandırıldığında ortaya çıkan yoksunluk semptomlarının nispeten hafif düzeyde olduğu bulunmuştur. Bu inceleme, lurasidonun şizofreni, şizoafektif bozukluk ve bipolar bozukluğu olan çocuklar ve ergenlerdeki kullanımına dair mevcut kanıtları ortaya koymaktadır. Mevcut veriler, lurasidonun özellikle olumlu metabolik profili ve genel tolere edilebilirliği sayesinde çocuklar ve ergenlerde şizofreni ve bipolar depresyon tedavisinde umut verici bir seçenek olduğunu göstermektedir. Bununla birlikte, mevcut çalışmaların sayısı ve kapsamı sınırlıdır. Bulguların doğrulanması, uzun dönem güvenliğin netleştirilmesi ve pediyatrik popülasyonda lurasidon kullanımına ilişkin kanıta dayalı klinik kılavuzların oluşturulabilmesi için daha geniş örneklemlerle, iyi tasarlanmış randomize kontrollü çalışmalara ihtiyaç vardır.

Anahtar Kelimeler: Lurasidon, tedavi, psikopatoloji, çocuk ve ergen

Address for Correspondence/Yazışma Adresi: Assoc. Prof., Berkan Şahin, Giresun University Faculty of Medicine, Department of Child and Adolescent Psychiatry, Giresun, Türkiye

E-mail: mail.berkan@gmail.com **ORCID:** orcid.org/0000-0003-4699-3418

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Introduction

Mental health disorders are a significant public health concern in childhood and adolescence, with psychiatric conditions during this period having profound individual and societal consequences. Managing psychiatric disorders in children and adolescents presents greater challenges compared to adults' treatment, as the developing brain may respond differently to pharmacological interventions. Therefore, the effectiveness and safety of medications in this population must be thoroughly assessed. Second-generation antipsychotics (SGAs) are essential in managing severe psychiatric disorders, including schizophrenia and bipolar disorder.[1]

Lurasidone is a novel antipsychotic that has demonstrated effectiveness in both preventing relapses and treating acute schizophrenia. It is distinguished from other SGAs by its unique pharmacological profile, particularly its action on 5-HT7 and 5-HT1A receptors.[2] The European Medicines Agency (EMA) has approved lurasidone for the treatment of schizophrenia in adults and adolescents between the ages of 13 and 17. Additionally, the Food and Drug Administration (FDA) in the United States has approved it for the treatment of bipolar disorder and schizophrenia.[3]

Among antipsychotics used in early-onset schizophrenia, lurasidone is one of five medications (along with aripiprazole, risperidone, paliperidone, and quetiapine) that have demonstrated both efficacy and safety.[4] It has a good tolerability profile and has little impact on body weight, prolactin levels, or metabolic parameters.[5] Given the metabolic risks associated with other antipsychotics, lurasidone represents an important treatment option due to its efficacy and low side effect burden.

This review will provide a comprehensive analysis of the current evidence on lurasidone use in children and adolescents, focusing on its efficacy, safety profile, clinical applications, and comparisons with alternative treatments. By addressing gaps in the literature, we aim to highlight future research directions and explore lurasidone's potential to improve both symptoms and quality of life in this vulnerable population.

Pharmacological Profile

With binding affinities of 0.99, 0.47, and 0.50 nM for dopamine D2, serotonin 5-HT2A, and 5-HT7 receptors, respectively, lurasidone is a benzoisothiazole derivative.[6] Lurasidone blocks the alpha-2c and alpha-2a adrenergic receptors with binding affinities of 10.80 and 40.70 nM, respectively, and is a complete antagonist at the D2, 5-HT2A, and 5-HT7 receptors.[2,6] Lurasidone is also a partial agonist at the 5-HT1A receptor, with a binding affinity of 6.38 nM.[2]

The antipsychotic and antidepressant effects of lurasidone are based on these interactions.[7] Full antagonism at mesolimbic D2 receptors is useful in treating positive symptoms of schizophrenia, including delusions and hallucinations. Lurasidone also functions as an antagonist at the serotonin 5-HT2A receptor. Through this effect, it disinhibits dopamine neurons, leading to an increase in dopamine release. Dopamine competes with the antipsychotic activity at the D2 receptors, exhibiting D2 antagonistic effects. The enhanced tolerability profile of lurasidone is linked to this mechanism of action, which decreases antagonistic binding in several dopaminergic pathways.[8-11] To lessen extrapyramidal symptoms, lurasidone targets the nigrostriatal pathway. Additionally, antagonism at the 5-HT2A receptors alleviates serotonergic stimulation of cortical pyramidal cells.[9-11] Lurasidone's antagonism at the 5-HT7 receptor may enhance learning and memory while also contributing to the alleviation of cognitive impairments and depressive symptoms.[12,13] The antidepressant properties of lurasidone may also be due to partial agonism at the 5-HT1A receptor.[2]

Pharmacodynamics and Metabolism

After oral administration, lurasidone is quickly absorbed; it takes about three hours for its plasma concentration to reach its peak. Between 9% and 19% of the given dose was absorbed, according to a study done on healthy adult volunteers. Up to 100 mg per day in healthy volunteers and up to 160 mg per day in schizophrenia patients, the absorption was linear.[14] In a pharmacokinetic study, the time to peak plasma concentration in healthy volunteers ranged from an average of 2.2 to 18.3 hours for doses up to 100 mg/day, reaching 36 hours at steady state.[14]

After a single dose of 120-160 mg/day, the plasma elimination half-life in adults with schizophrenia varied from 8.8 to 37.4 hours. According to a study that looked at patients with schizophrenia or schizoaffective disorder who received multiple doses of 120 mg per day, steady-state plasma levels were reached by day five.[15] Within one to three hours after taking 40 mg orally, lurasidone reaches its peak plasma concentration. It takes seven days of continuous administration to reach steady-state levels. Lurasidone primarily binds to plasma proteins, including albumin and alpha-1 acid glycoprotein, after absorption.[14]

Cytochrome P (CYP) 450 3A4 is the primary metabolic enzyme for lurasidone; it is not a substrate for CYP1A1, 1A2, 2A6, 4A11, 2B6, 2C8, 2C9, 2C19, 2D6, or 2E1. S-oxidation, hydroxylation of the norbornane ring, and oxidative N-dealkylation are the primary metabolic processes of lurasidone. Two pharmacologically active metabolites are produced by these metabolic processes: ID-14283 (the exohydroxy metabolite), which contributes about 25% of primary exposure, and ID-14326, which makes up about 3%. A third minor active metabolite, ID-11614, constitutes approximately 1% of exposure.[14,15] Lurasidone does not induce or inhibit CYP enzymes. Furthermore, lurasidone's primary active metabolite, ID-14283, has a shorter half-life than the drug itself. About 80% of lurasidone is eliminated through feces, 9.2% through urine, and the remaining 10.7% through unknown means. Patients with hepatic and renal insufficiency need to have their doses monitored. Furthermore, lurasidone is one of the few SGAs whose absorption is significantly influenced by food intake. When administered with a meal containing approximately 350 calories, its bioavailability increases substantially, whereas fasting conditions markedly

reduce systemic exposure. This pharmacokinetic feature has important clinical implications, as patients are advised to take lurasidone with food to ensure optimal therapeutic efficacy.

Dosage and Application

Lurasidone comes in 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg extended-release tablet forms. All dosages are accessible in Türkiye. 40 mg daily is the recommended starting dose for treating schizophrenia in adults and adolescents, with a daily maximum of 80 mg for adolescents and 160 mg for adults.[16] For the treatment of bipolar depression, the recommended starting dose for both adults and pediatric patients is 20 mg per day, with the dose being increased after one week if necessary. The maximum recommended dose for treatment is 120 mg per day for adults and 80 mg per day for adolescents.

For adults with moderate to severe renal impairment, treatment should be initiated at a dose of 20 mg/day, with dosage adjustments permitted up to a maximum of 80 mg/day.[16] These dosages may be cut in half for teenagers. Adults with severe hepatic impairment should take no more than 40 mg per day, with a starting dose of 20 mg. Doses for children should likewise be lowered appropriately. The recommended starting dose for moderate liver impairment is 20 mg per day, with a maximum dose of 80 mg per day; for severe liver impairment, the maximum recommended dose is 40 mg per day.[17] The primary CYP450 enzyme responsible for metabolizing lurasidone is CYP3A4. Consequently, the lurasidone dosage should be lowered to an initial 20 mg/day with a maximum of 80 mg/day, which is half the recommended dosage, when co-administered with moderate CYP3A4 inhibitors. Conversely, when administered alongside moderate CYP3A4 inducers, dosage adjustments may be required to ensure therapeutic effectiveness.

Adverse Effects

Studies on the adverse effects of lurasidone have shown that it poses fewer metabolic risks—such as hyperglycemia, hypercholesterolemia, hyperlipidemia, and weight gain—compared with quetiapine and the olanzapine/fluoxetine combination.[18] In a study evaluating the relationship between antipsychotic use and metabolic syndrome in children and adolescents, it was observed that antipsychotics generally pose a high risk of inducing lipid disorders; however, lurasidone and aripiprazole demonstrated a more neutral metabolic profile.[19]

A review examining the effects of lurasidone in adolescents identified somnolence, extrapyramidal symptoms, akathisia, and nausea as the most common side effects.[5] The majority of treatment-related side effects were mild to moderate in severity, with akathisia, nausea, and somnolence being the most frequent. This was the conclusion of a double-blind, placebo-controlled study evaluating lurasidone monotherapy for bipolar 1 depression in adult patients. Other common side effects in this study included nasopharyngitis and Parkinsonism, which were more common in the lurasidone groups than in the placebo groups.[20]

There were no clinically significant differences between the lurasidone and placebo groups in terms of changes in lipid, glucose, and prolactin levels, and the average change in QT interval was comparable, according to a study assessing the medication's safety and effectiveness in treating children and adolescents with bipolar I depression.[21] However, in studies assessing its effects in the acute phase, significant increases in prolactin levels were observed. Lurasidone was also associated with an approximate 7% increase in baseline body weight.[22] Additionally, findings indicate that lurasidone led to a 7% increase in baseline body weight.[23] It has been documented that lurasidone, especially when taken by pregnant patients in the third trimester, can cause withdrawal symptoms or extrapyramidal symptoms in newborns.[13,16]

A treatment guideline for the acute management of schizophrenia states that, in some cases, higher doses of antipsychotics may be required. While increased doses lead to greater postsynaptic dopamine receptor blockade—potentially reducing the antidepressant effect—they also heighten susceptibility to side effects. However, it has been suggested that lurasidone maintains its antidepressant properties even at higher doses, highlighting the need for individualized dose adjustments based on clinical response.[24]

Follow-up

For patients with hepatic and renal impairment, dose monitoring is crucial. Modifications are recommended for moderate to severe cases, but mild impairment does not require dosage adjustments. Additionally, using lurasidone with CYP3A4 inducers or inhibitors requires careful monitoring.

There are very few case reports linking lurasidone to anemia. Chronic and severe psychiatric disorders, including schizophrenia and bipolar disorder, can elevate the risk of anemia and nutritional deficiencies, largely due to inadequate dietary habits. Therefore, it is recommended that patients receiving lurasidone undergo blood count evaluations both at the beginning of treatment and during follow-up.[25]

Toxicity

There is little information on lurasidone overdose. Only one overdose case report has been found in a review of the current literature. In this instance, a male individual, age 31, attempted suicide by ingesting 8.5 times the recommended maximum dosage. The overdose occurred shortly after lunch, which may have enhanced lurasidone absorption. Following the high-dose intake, the patient developed mild hypertension and a slight elevation in thyroid-stimulating hormone (TSH) levels. Treatment consisted of intravenous fluids, and the patient recovered without long-term complications, with TSH levels returning to normal three weeks later.[26] Currently, no specific antidote exists for lurasidone. In the event of an overdose, patients should be closely monitored for QT interval prolongation, orthostatic hypotension, central nervous system depression, and tachycardia, with appropriate supportive care administered as needed.[27]

Efficacy and Safety

Considering the effectiveness and safety issues associated with medications used to treat schizophrenia and bipolar disorder, a cautious approach is necessary, especially when treating children and adolescents. There are currently few clinical studies on lurasidone's effectiveness in treating schizophrenia in children. Nonetheless, research on adults has demonstrated that lurasidone is superior to a placebo in terms of lowering symptoms of schizophrenia. These findings imply that children and adolescents may also experience comparable effectiveness. All things considered, lurasidone is generally well-tolerated and has a favorable metabolic side effect profile. It has also shown effectiveness in the acute and long-term management of schizophrenia.[19] The ability to adjust the dose according to clinical needs provides flexibility in the treatment process.

In a study, DelBello et al.[21] assessed the safety and effectiveness of lurasidone in treating adolescent bipolar depression. Patients with bipolar I depression who were between the ages of 10 and 17 were randomly assigned to receive either lurasidone or a placebo for six weeks, with a flexible dosage range of 20 to 80 mg per day. The main outcome measure was the change in the overall score on the Children's Depression Rating Scale-Revised (CDRS-R) between baseline and week six. The results showed that, in comparison to the placebo, lurasidone resulted in a statistically significant improvement in the CDRS-R total score at week six. Additionally, lurasidone demonstrated improvements in secondary outcome measures, including the Clinical Global Impressions-bipolar severity of depression score, anxiety levels, quality of life, and overall functioning.

A recent study was carried out to assess how children and adolescents with bipolar depression responded to lurasidone treatment, sleep disturbances, and irritability.[19] Lurasidone was given in flexible doses ranging from 20 to 80 mg/day to 347 children and adolescents with bipolar I depression in this randomized, placebo-controlled study. Young people with DSM-5 bipolar I depression, with or without rapid cycling and psychotic features, who were between the ages of 10 and 17 were included in the study. During a six-week, double-blind treatment phase, these participants were randomly assigned to receive either a placebo or flexible doses of lurasidone (20-80 mg). At both the screening and baseline evaluations, eligible participants had to have a Young Mania Rating Scale (YMRS) item 1 (elevated mood) score of less than 2 and a total score of less than 15. The Children's Global Assessment Scale (CGAS), YMRS, and the CDRS-R were used to evaluate the outcome measures in this analysis. In this study, bridge symptoms—which are common and disruptive in bipolar depression—were identified as a decrease in sleep needs and irritability. By the sixth week of lurasidone treatment, it was discovered that improvements in manic and depressive symptoms were mediated by a decrease in irritability and sleep requirements. Low CDRS-R and high CGAS scores persisted throughout the course of treatment. After two years of lurasidone treatment, a significantly higher percentage of participants without bridge symptoms—such as reduced sleep needs and irritability—achieved sustainable improvement criteria at the conclusion of the 6-week acute treatment period than those who did not. Treatment with lurasidone improved the cluster of depressive symptoms more than it did the key manic symptoms.[19]

A publication from 2024 exploring advancements in the diagnosis and treatment of pediatric bipolar disorder highlights lurasidone's potential to significantly reduce depressive symptoms while being a preferred option due to its minimal impact on weight.[28] Research has shown that lurasidone significantly improves depression scores when compared to placebo groups, effectively reducing depressive symptoms in patients with bipolar I depression.[19,21,23] With few adverse effects and little effect on weight or metabolic parameters, lurasidone has also been well tolerated.

To provide a structured overview of the current evidence, Table 1 summarizes the main clinical studies investigating lurasidone use in children and adolescents. The table presents study populations, design, key outcomes, and reported adverse events. As seen, most trials focus on schizophrenia and bipolar I depression, consistently demonstrating lurasidone's favorable efficacy and tolerability profile, particularly regarding metabolic safety. Nonetheless, the limited number of randomized controlled trials underscores the need for further research to consolidate these findings.

Comparison with Other Antipsychotics in Treatment

Only a limited number of randomized clinical trials have compared the efficacy and tolerability of atypical antipsychotics in patients younger than 18 years.[11,29] Lurasidone is significantly more effective than placebo, as measured by the Positive and Negative Syndrome Scale and Clinical Global Impressions-severity (CGI-S) scales, and to have comparable efficacy to other oral atypical antipsychotics in adolescents with schizophrenia.[11] In this study, adolescents treated with lurasidone experienced fewer withdrawal symptoms than those treated with aripiprazole and paliperidone estrogen receptor (ER), and participants showed statistically significantly less weight gain than those treated with quetiapine, olanzapine, risperidone, asenapine, or paliperidone ER. Lurasidone and other antipsychotics did not significantly differ in their risk of akathisia or extrapyramidal symptoms. Compared to the majority of atypical antipsychotics, lurasidone has a lower risk of weight gain and appears to be an effective treatment for adolescents with schizophrenia, according to these findings.[11]

The use of atypical antipsychotics in bipolar disorder was the subject of a 2021 review that searched MEDLINE, EMBASE, PsycINFO, and ClinicalTrials.gov for studies published between January 2017 and July 2020 without regard to language limitations. The mean decreases in depressive and manic symptoms, as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS), Hamilton Depression Rating Scale, and YMRS, as well as the overall severity measured by the CGI-S scale, were the main outcomes in studies on acute bipolar

depression and bipolar mania. Remission rates (defined as MADRS total score ≤8, YMRS total score ≤12, or CGI-S ≤2), response rates (defined as ≥50% reduction from baseline in total YMRS or MADRS score), treatment discontinuation rates, treatment discontinuation due to side effects, and the incidence of any adverse events were examples of secondary outcomes. In the maintenance treatment of bipolar disorder, lurasidone is assumed to be more successful in preventing depressive episodes than manic episodes. Similar weight changes were noted between the lurasidone and placebo treatment groups, and nausea and sedation were the most frequently reported side effects. According to analyses, patients receiving lurasidone had a noticeably lower recurrence rate of depressive episodes. Lurasidone monotherapy, at a dose of 20-80 mg daily, has been demonstrated to be a successful and well-tolerated treatment for acute depression in patients with bipolar disorder who are not responding to treatment.[30]

In 2023, a thorough systematic review and meta-analysis of randomized controlled trials involving antipsychotic drugs for individuals with unipolar and bipolar depression aged 10 to 25 was carried out. The four randomized controlled trials selected for inclusion focused on adolescents diagnosed with bipolar depression. All studies compared antipsychotic drug treatment with placebo and used the CDRS-R to measure depressive symptoms. In the study that included lurasidone, it was found to be effective and well-tolerated with good safety in bipolar depression.[31] Lurasidone seemed neutral for all glucose and lipid-related outcomes in adults with bipolar depression, and its use in adolescents was thought to be more beneficial, according to the first umbrella review, which was published in 2023 and methodically and quantitatively documented the effects of pharmacological and non-pharmacological interventions on physical health outcomes in mood disorder patients.[32]

Expert Opinion

Lurasidone has proven to be effective in both lowering the chance of relapse and treating schizophrenia acutely. Numerous symptoms of schizophrenia, including positive, negative, and cognitive symptoms, have been demonstrated to improve with it. As a result, it might be a suitable choice for treating schizophrenia patients in a customized manner.[33] Lurasidone also has a good tolerability profile, with little effect on prolactin levels, weight gain, or metabolic parameters. Patients with bipolar I depression have shown significant reductions in depressive symptoms when taking lurasidone at doses ranging from 20 to 120 mg/day.[31] Given this data and the increasing number of adolescent studies, it is considered an antipsychotic that can be safely used in the adolescent population.

Limitations and Future Directions

Despite the growing clinical interest in lurasidone for children and adolescents, the current body of evidence remains limited. Most available data are derived from a small number of randomized controlled trials with relatively short follow-up periods, which restricts the ability to draw firm conclusions about long-term efficacy and safety. Furthermore, existing studies often include heterogeneous samples, and there is a lack of head-to-head comparisons with other SGAs commonly used in pediatric psychiatry. Another limitation is the underrepresentation of certain diagnostic categories, such as schizoaffective disorder and comorbid conditions, which are frequently encountered in real-world clinical settings.

Future research should therefore prioritize large-scale, multicenter randomized controlled trials with extended follow-up to better characterize the efficacy, safety, and tolerability of lurasidone in diverse pediatric populations. Comparative effectiveness studies against other antipsychotics are also warranted to guide evidence-based prescribing practices. In addition, studies focusing on long-term metabolic outcomes, cognitive functioning, and quality of life will be crucial to fully assess the clinical utility of lurasidone. Finally, real-world evidence and naturalistic studies may complement controlled trials by capturing treatment effectiveness and tolerability in everyday clinical practice.

Key Information

Lurasidone is approved by the FDA to treat bipolar disorder (ages 10-17) and schizophrenia (ages 13-17) in adults and adolescents (ages 13-17), as well as by the EMA. Lurasidone comes in 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg tablet forms. It is quickly absorbed, and CYP3A4 metabolizes it. Lurasidone has little effect on body weight, prolactin levels, or metabolic parameters and is well tolerated.

Conclusion

In the treatment of bipolar depression and schizophrenia, lurasidone has proven to be effective, reliable, and tolerable. Its side effect profile is also generally better than that of other antipsychotic medications. Its pharmacokinetic advantages include rapid absorption following oral administration, a short time to achieve steady-state concentration, and a lack of significant interactions with enzyme systems (e.g., minimal inhibition or induction of CYP450 enzymes). Additionally, lurasidone has demonstrated potential as a monotherapy option for bipolar disorder that is resistant to treatment. It has the dual advantage of preventing the need for high-dose antipsychotic regimens and offering antidepressant effects at higher doses for the acute treatment of schizophrenia.

Despite these advantages, there remains a need for further clinical research to evaluate the efficacy and safety of lurasidone in pediatric and adolescent populations. Future studies should focus on elucidating both the short- and long-term outcomes of lurasidone treatment in these younger age groups. Additionally, research should explore its effectiveness across diverse diagnostic categories and varying levels of symptom severity. Importantly, the treatment of children and adolescents with lurasidone should not be confined to pharmacological interventions alone. A holistic, multidisciplinary approach that integrates psychosocial and

Table 1. Summary of clinical studies of lurasidone in children and adolescents

First author (year)	Population (age, n)	Design	Disorder/ indication	Key findings	Adverse effects
DelBello et al. (2017)[21]	Adolescents 10-17 yrs, n=347	RCT, double-blind, placebo-controlled, 6 weeks, flexible dose 20-80 mg/day	Bipolar I depression	Significant reduction in CDRS-R scores vs placebo; improvement in CGI-BP, anxiety, and quality of life	Somnolence, nausea, akathisia, extrapyramidal symptoms (mostly mild/ moderate)
Loebel et al. (2014)[23]	Adolescents 13-17 yrs (part of sample included adults), n≈326	RCT, double-blind, placebo-controlled	Schizophrenia	Lurasidone significantly reduced PANSS and CGI-S scores; efficacy comparable to other SGAs	Akathisia, somnolence, nausea; lower risk of weight gain vs quetiapine/ olanzapine
Kato et al. (2020)[20]	Adolescents & adults (subgroup 10-17 yrs analyzed separately), n≈463	RCT, double-blind, placebo-controlled, 6 weeks	Bipolar I depression	Significant improvement in depressive symptoms on CDRS-R; consistent efficacy across pediatric subgroups	Nausea, akathisia, somnolence; metabolic parameters largely unchanged
Singh et al. (2023)[19]	Adolescents 10-17 yrs, n=347 (secondary analysis of DelBello et al.[21] 2017 trial)	Post-hoc analysis	Bipolar I depression	Improvement in sleep disturbance and irritability mediated antidepressant response; better functional outcomes.	Similar safety profile: akathisia, somnolence, nausea
Arango et al. (2020)[30]	Adolescents with schizophrenia, 13-17 yrs, n varies across pooled trials	Systematic review & network meta-analysis	Schizophrenia	Lurasidone showed efficacy comparable to risperidone, aripiprazole, and paliperidone; better weight/metabolic profile.	Lower risk of weight gain, neutral metabolic profile
Fiorillo et al. (2022)[5]	Adolescents & adults with schizophrenia, real-world data	Narrative review + real-world observations	Schizophrenia	Confirmed efficacy in symptom reduction; good tolerability in clinical practice	Mild EPS, low weight gain risk
Garcia-Rodriguez et al. (2023)[31]	Adolescents/young adults 10-25 yrs, meta-analysis of RCTs	Systematic review & meta-analysis	Unipolar & bipolar depression	Lurasidone effective and well-tolerated in pediatric bipolar depression	Neutral metabolic profile, low discontinuation rates
Carnovale et al. (2024)[34]	Children/adolescents with psychosis or bipolar disorders	Umbrella review	Metabolic safety	Lurasidone among SGAs with the lowest metabolic risk in youth	Minimal impact on weight, lipids, and glucose

CGI-BP: Clinical Global Impressions-bipolar, PANSS: Positive and Negative Syndrome Scale, RCT: Randomized controlled trial, CDRS-R: Children's Depression Rating Scale-Revised, CGI-S: Clinical Global Impressions-severity, SGA: Second-generation antipsychotic

behavioral strategies may optimize therapeutic outcomes in this vulnerable population. The development of comprehensive clinical guidelines and tailored treatment protocols could further enhance the success of lurasidone-based therapies in pediatric psychiatric care.

Footnotes

Authorship Contributions

Concept: B.S.Ö., C.Ö., B.Ş., C.Ç.O., Design: B.S.Ö., C.Ö., B.Ş., C.Ç.O., Data Collection or Processing: B.S.Ö., C.Ö., B.Ş., C.Ç.O., Analysis or Interpretation: B.S.Ö., C.Ö., B.Ş., C.Ç.O., Literature Search: B.S.Ö., C.Ö., B.Ş., C.Ç.O., Writing: B.S.Ö., C.Ö., B.Ş., C.Ç.O.

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