Okedi®

Risperidone prolonged-release suspension for injection **75 mg, 100 mg**

Dosing card

Instructions for the **dosing** and **administration** of OKEDI®

For UK Healthcare Professionals only
Prescribing information can be found at the end of the material

UK-OKE-23-11/0006

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OKEDI®, with **innovative ISM technology,** is a **convenient** 4-weekly long-acting injectable antipsychotic from ROVI

INDICATED FOR THE TREATMENT OF SCHIZOPHRENIA IN ADULTS

for whom tolerability and effectiveness with oral risperidone have been established[1]

OKEDI® is available as:

OKEDI® 75 mg
Powder and solvent for prolonged-release suspension for injection

OKEDI® 100 mg
Powder and solvent for prolonged-release suspension for injection

OKEDI® does not require oral supplementation or loading doses.[1]

- OKEDI® should be administered every 28 days by **intramuscular (IM) deltoid or gluteal** injection.[1]
- OKEDI® **does not require refrigeration** and can be stored below 30°C.[1]

POSOLOGY

OKEDI® should be initiated on an individual patient basis taking into consideration clinical presentation and previous treatment history[1]

Patients with history of **previous response to risperidone currently stabilised with oral antipsychotics[1]**

Stabilised with **oral risperidone**	Direct switch to **OKEDI® 75 or 100 mg**
Stabilised with **other oral antipsychotics**	At least **6 days** of oral risperidone before administering **OKEDI® 75 or 100 mg**

Patients **never treated before with oral risperidone[1]**

At least **14 days** of oral risperidone before administering **OKEDI® 75 or 100 mg**

Patients currently on **risperidone bi-weekly long-acting injection[1]**

Direct switch to OKEDI® 75 or 100 mg every 28 days

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RECOMMENDED DOSES

Switching from risperidone bi-weekly LAI to OKEDI®[1]

37.5 mg of risperidone bi-weekly LAI	50 mg of risperidone bi-weekly LAI
OKEDI® 75 mg every 4 weeks	**OKEDI® 100 mg** every 4 weeks

OKEDI® does not require oral supplementation or loading doses.[1]

- OKEDI® should be initiated in place of the next regularly scheduled injection of risperidone bi-weekly LAI (i.e., two weeks after the last risperidone bi-weekly LAI).
- OKEDI® should be then administered at 28-day intervals.[1]

LAI: Long-acting injectable.

Switching from oral risperidone to OKEDI®[1]

3 mg/day of oral risperidone	4 mg/day or higher of oral risperidone
OKEDI® 75 mg every 4 weeks	**OKEDI® 100 mg** every 4 weeks

OKEDI® does not require oral supplementation or loading doses[1]

OKEDI® must be initiated approximately 24 hours after the last oral risperidone dose.[1]

- Dose adjustments of OKEDI® may be made every 28 days.[1]
- A maintenance dose of OKEDI® 75 mg every 28 days is generally recommended. However, some patients may benefit from the 100 mg dose, according to the patient's clinical response and tolerability.[1]

Switching from OKEDI® back to oral risperidone[1]

- When switching patients from OKEDI® injection back to oral risperidone, it is recommended to start oral risperidone treatment 28 days after the last OKEDI® administration.[1]

SPECIAL POPULATIONS[1]

ELDERLY

- Efficacy and safety of OKEDI® in elderly > 65 years have not been established for OKEDI®[1]
- OKEDI® should be used with caution in elderly.[1]
- Recommended dosing of risperidone for elderly patients with normal renal function is the same as for adult patients with normal renal function.[1]

RENAL IMPAIRMENT

- OKEDI® has not been systematically studied in patients with renal impairment.[1]
- For patients with mild renal impairment (creatinine clearance 60 to 89 mL/min), no dose adjustment is required for OKEDI®.[1]
- OKEDI® is not recommended in patients with moderate to severe renal impairment (creatinine clearance < 60 mL/min).[1]

HEPATIC IMPAIRMENT

- OKEDI® has not been systematically studied in patients with hepatic impairment.[1]
- OKEDI® should be used with caution in these groups of patients.[1]
- A careful titration with oral risperidone (halving starting doses and slowing titration) before initiating treatment with OKEDI® at a dose of 75 mg is recommended, if tolerability of an oral dose of at least 3 mg is confirmed.[1]

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MISSED DOSES[1]

TO AVOID A MISSED DOSE, patients may be given OKEDI® **up to 3 days before** the 28-day time point.[1]
If a dose is delayed by 1 week, the median trough concentration decreases by approximately 50% during that week.

IF THE DOSE IS DELAYED, the next 28-day interval injection should be scheduled according to the date the last injection was given.[1]

IF A DOSE IS INCORRECTLY ADMINISTERED by intravenous or subcutaneous route, the dose should not be repeated since it is difficult to estimate the resulting exposure to the medicine.[1]

1. **OKEDI** SmPC

OKEDI® 75 mg and 100 mg powder and solvent for prolonged release suspension for intramuscular (IM) injection Prescribing information.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each pre-filled syringe contains 75 mg or 100 mg risperidone **Indication:** OKEDI is indicated for the treatment of schizophrenia in adults for whom tolerability and effectiveness to risperidone have been established. **Posology and Method of Administration:** OKEDI should be administered by a qualified healthcare provider and ***initiated according to the patient's clinical context - see SmPC for detailed guidance.*** Administer OKEDI every 28 days by IM deltoid or gluteal injection. For full details on the preparation, reconstitution, and administration, see *'Instructions for healthcare professionals'* provided in the package leaflet. A maintenance dose of OKEDI 75 mg every 28 days is generally recommended. Some patients may benefit from OKEDI 100 mg every 28 days according to clinical response and tolerability. Neither a loading dose nor supplemental oral risperidone is recommended. **Elderly:** safety and efficacy of OKEDI for patients > 65 years have not been established. **Renal impairment: Mild** (creatinine clearance 60 to 89 mL/min) no dose adjustment required. **Moderate or severe** (creatinine clearance <60mL/min) not recommended. **Hepatic impairment:** use with caution. **CONTRAINDICATIONS:** Hypersensitivity to risperidone or any excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Establish tolerability to oral risperidone prior to OKEDI. Rarely, anaphylactic reactions are reported in patients previously tolerating oral risperidone. If this occurs with OKEDI, discontinue treatment, initiate general supportive measures and monitor until resolved. Do not use in elderly patients with dementia. Caution in cerebrovascular disease, hypotension, cardiovascular disease (including family history of, or known QT prolongation), Parkinson's Disease, Lewy body dementia, seizures, and prolactin-dependent tumours. Monitoring of white blood cell count (WBC) may be needed. Discontinue OKEDI if a clinically significant decline in WBC occurs without other cause. If tardive dyskinesia occurs, consider discontinuation of all antipsychotics. Caution required in patients receiving concomitant psychostimulants (e.g., methylphenidate) and risperidone. Gradual withdrawal of psychostimulant recommended. Discontinue OKEDI if neuroleptic malignant syndrome occurs. Discontinue OKEDI if Stevens-Johnson syndrome/toxic epidermal necrolysis occurs. Weight gain is common. Monitor patients with, or at risk, of diabetes. Patients with prolonged priapism should seek urgent medical care. Body temperature dysregulation may occur. An antiemetic effect may mask signs and symptoms of other conditions including overdoses. Identify risk factors for venous thromboembolism and take preventative measures. Intraoperative floppy iris syndrome may increase cataract surgery complications. **Interactions with other medicinal products:** No interaction studies have been performed with OKEDI. See SmPC for extensive interaction data based on oral risperidone studies. **Pregnancy and breast feeding:** Should not be used during pregnancy unless clearly necessary. A risk to the breastfed child cannot be excluded. **Undesirable effects:** The most frequent adverse drug reactions reported in an OKEDI phase 3 trial were blood prolactin increased (11.7%), hyper-prolactinaemia (7.2%), akathisia (5.5%), headache (4.8%), somnolence (4.1%), weight increased (3.8%), injection site pain (3.1%) and dizziness (3.1%). **Refer to the SmPC for other adverse reactions reported for risperidone from clinical trials and post marketing experience with risperidone medicinal products.**

Legal Category: Prescription Only Medicine (POM)

Presentation and Basic NHS cost: OKEDI 75 mg pack containing one pre-filled syringe - £222.64 OKEDI 100 mg pack containing one pre-filled syringe - £285.52.

Marketing Authorisation (MA) Numbers: PLGB 15406/0018 (75 mg), PLGB15406/0019 (100 mg) MA Holder: Laboratorios Farmacéuticos Rovi, S.A., Julián Camarillo, 35, 28037 Madrid, Spain Date of Preparation: November 2023

UK-OKE-23-11/0002

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6. **Yildiz M.** Psychosocial rehabilitation interventions in the treatment of schizophrenia and bipolar disorder. Noro Psikiyatr Ars. 2021 Sep 20;58(Suppl 1):S77-S82

For further information about Okedi® please contact your local ROVI Key Account Manager

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Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/**

Or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should be reported to **uk-pharmacovigilance@rovi.com** Or by telephone Tel: +44 (0) 203 642 0677

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OKEDI® is indicated for the treatment of schizophrenia in adults for whom tolerability and effectiveness have been established with oral risperidone[1]

A PATH FOR YOUR PATIENTS FROM DAY 1[1,2]

No need for oral supplementation or loading doses which may improve the therapeutic alliance[1,3]

- **Achieving therapeutic plasma levels similar to oral risperidone from Day 1, that are sustained throughtout the 28-day dosing period[4]**
- **No requirement for oral supplementation or loading doses[1]**
- **Generally well tolerated in a 12-month** open-label extension study[5]
- **May help improve adherence, allowing a focus on patients´ psychosocial recovery[5,6]**