SUMMARY OF PRODUCT CHARACTERISTICS
VORZI 10 mg Film-Coated Tablets

1. NAME OF THE MEDICINAL PRODUCT

VORZI 10 mg Film-Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains vortioxetine hydrobromide equivalent to vortioxetine 10 mg.

Excipients with known effect:

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet — essentially sodium-free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White coloured, almond shaped, biconvex, film-coated tablet debossed with "V" on one side and "10" on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VORZI 10 mg is indicated for the treatment of major depressive episodes (MDE) in adults.

4.2 Posology and method of administration

Recommended dose

VORZI 10 mg is the recommended starting and maintenance dose in adults below 65 years of age. The dose may be increased to VORZI 20 mg or decreased to VORZI 5 mg based on individual patient response.

Adults below 65 years

The recommended starting and maintenance dose of vortioxetine is 10 mg once daily. Based on individual patient response, the dose may be increased to a maximum of 20 mg once daily or decreased to a minimum of 5 mg once daily. After resolution of depressive symptoms, treatment for at least 6 months is recommended to consolidate the antidepressant response. Treatment can be discontinued without gradual dose reduction.

Elderly patients (≥65 years)

The recommended starting dose is 5 mg vortioxetine once daily. Caution is advised when treating patients ≥65 years with doses higher than 10 mg once daily (see section 4.4).

CYP2D6 inhibitors

A lower dose of vortioxetine may be considered if a strong CYP2D6 inhibitor (e.g. bupropion, quinidine, fluoxetine, paroxetine) is added to vortioxetine treatment (see section 4.5).

CYP2D6/3A4 inducers

A dose adjustment may be considered if a broad cytochrome P450 inducer (e.g. rifampicin, carbamazepine, phenytoin) is added to treatment (see section 4.5).

Renal or hepatic impairment

No dose adjustment is needed based on renal or hepatic function (see sections 4.4 and 5.2).

Paediatric population

VORZI is not recommended for children aged 7–11 years (safety and efficacy not established) and should not be used in adolescents aged 12–17 years with MDD (efficacy has not been demonstrated).

Method of administration

For oral use. May be taken with or without food.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

- Concomitant use with non-selective monoamine oxidase inhibitors (MAOIs) or selective MAO-A inhibitors (see section 4.5).

4.4 Special warnings and precautions for use

Paediatric population

VORZI is not recommended for children aged 7–11 years. VORZI should not be used in adolescents aged 12–17 years with MDD as efficacy has not been demonstrated. In clinical studies in children and adolescents, suicide-related behaviour and hostility were more frequently observed with antidepressants than with placebo.

Suicide/suicidal thoughts and clinical worsening

Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide. This risk persists until significant remission occurs. Patients should be closely monitored until improvement occurs. Patients with a history of suicide-related events or exhibiting significant suicidal ideation are at greater risk. Patients (and caregivers) should be alerted to monitor for any clinical worsening, suicidal behaviour or unusual changes in behaviour and to seek medical advice immediately.

Serotonin syndrome / Neuroleptic malignant syndrome (NMS)

Potentially life-threatening conditions, including SS and NMS, may occur. The risk is increased with concomitant use of serotonergic substances (including triptans), MAOIs, antipsychotics and other dopamine antagonists. If SS or NMS occurs, discontinue vortioxetine immediately and initiate symptomatic treatment.

Seizures

Vortioxetine should be introduced cautiously in patients with a history of seizures or with unstable epilepsy. Discontinue if seizures develop or seizure frequency increases.

Mania/hypomania

Use with caution in patients with a history of mania/hypomania; discontinue if a manic episode occurs.

Haemorrhage

Bleeding abnormalities have been reported rarely. Caution in patients taking anticoagulants, antiplatelet agents, or with known bleeding tendencies. Potential increased risk of postpartum haemorrhage (see section 4.6).

Hyponatraemia

Hyponatraemia (probably due to SIADH) has been reported rarely. Caution in at-risk patients (elderly, cirrhosis, medicines causing hyponatraemia). Consider discontinuation if symptomatic hyponatraemia occurs.

Angle-closure glaucoma

Mydriasis has been reported; this may increase intraocular pressure in susceptible patients.

Elderly

Data on use in patients ≥65 years are limited. Caution is advised with doses >10 mg once daily in this age group.

Renal or hepatic impairment

Given the vulnerability of these patient groups and limited data, caution is advised.

4.5 Interaction with other medicinal products and other forms of interaction

Vortioxetine is primarily metabolised by CYP2D6 (and to a lesser extent CYP3A4/5 and CYP2C9).
MAOIs (contraindicated):

Due to risk of serotonin syndrome, concomitant use with irreversible non-selective MAOIs is contraindicated; a minimum 14-day washout is required before or after. Concomitant use with reversible selective MAO-A inhibitors (moclobemide) and reversible non-selective MAOIs (linezolid) is also contraindicated.

Irreversible selective MAO-B inhibitors (selegiline, rasagiline):

Should be used with caution; close monitoring for serotonin syndrome is necessary.

Strong CYP2D6 inhibitors (bupropion, quinidine, fluoxetine, paroxetine):

Vortioxetine AUC increased 2.3-fold when co-administered with bupropion. A lower dose of vortioxetine may be considered (see section 4.2).

CYP3A4/5 inhibitors and CYP2C9/2C19 inhibitors:

Resulted in 1.3–1.5-fold increases in vortioxetine AUC. No dose adjustment needed.

Broad CYP inducers (rifampicin, carbamazepine, phenytoin):

Rifampicin caused a 72% decrease in vortioxetine AUC. A dose adjustment may be considered (see section 4.2).

Serotonergic medicinal products; St. John's Wort:

Risk of serotonin syndrome. Concomitant use should be undertaken with caution.

Anticoagulants/antiplatelet agents:

No significant pharmacokinetic interaction with warfarin or aspirin, but caution is advised due to a potential pharmacodynamic bleeding risk (see section 4.4).

Vortioxetine in vitro did not inhibit or induce cytochrome P450 isozymes. No significant effects on OCs, omeprazole, diazepam, warfarin, caffeine or dextromethorphan pharmacokinetics. Urine drug screens: false positive results for methadone have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

Limited data from vortioxetine use in pregnant women. The following symptoms may occur in the newborn after maternal use of a serotonergic medicinal product in the later stages of pregnancy: respiratory distress, cyanosis, apnoea, seizures, temperature instability, feeding difficulty, hypoglycaemia, hypertonia, hypotonia, hyperreflexia, tremor, jitteriness, irritability, lethargy. Risk of postpartum haemorrhage and possible increased risk of persistent pulmonary hypertension in the newborn cannot be excluded. VORZI should only be used during pregnancy if the expected benefit outweighs the potential risk to the foetus.

Breast-feeding

Vortioxetine is expected to be excreted into human milk. A risk to the breast-feeding child cannot be excluded. A decision must be made whether to discontinue breast-feeding or discontinue VORZI treatment, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

Fertility studies in male and female rats showed no effect on fertility, sperm quality or mating performance. Human case reports with related pharmacological classes (SSRIs) have shown a reversible effect on sperm quality.

4.7 Effects on ability to drive and use machines

VORZI has no or negligible influence on the ability to drive and use machines. However, as dizziness has been reported, patients should exercise caution when driving or operating hazardous machinery, especially when starting treatment or when the dose is changed.

4.8 Undesirable effects

Summary of the safety profile

The most common adverse reaction is nausea, which is generally mild to moderate in severity, occurs within the first two weeks of treatment and is usually transient. Gastrointestinal adverse reactions occur more frequently in women than in men.

System Organ Class	Very common	Common	Uncommon	Rare/Not known
Immune system				Anaphylactic reaction (NK)
Endocrine				Hyperprolactinaemia (NK)
Metabolism				Hyponatraemia (NK)
Psychiatric		Abnormal dreams		Insomnia; agitation, aggression (NK)
Nervous system		Dizziness		Serotonin syndrome; headache (NK)
Eye				Mydriasis — angle-closure glaucoma risk (Rare)
Vascular			Flushing	Haemorrhage (NK)
Gastrointestinal	Nausea	Diarrhoea, constipation, vomiting		

System Organ Class	Very common	Common	Uncommon	Rare/Not known
Skin		Pruritus (incl. generalised), hyperhidrosis	Night sweats	Angioedema, urticaria, rash (NK)

NK = not known (frequency cannot be estimated from available data; based on post-marketing cases). Dose-related bone fracture risk has been reported as a class effect for serotonergic antidepressants. Paediatric population: higher incidences of abdominal pain-related events and suicidal ideation compared with adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

Ingestion of vortioxetine 40–75 mg has caused aggravation of nausea, postural dizziness, diarrhoea, abdominal discomfort, generalised pruritus, somnolence and flushing. Post-marketing experience mainly concerns overdoses up to 80 mg (mostly no or mild symptoms; most commonly nausea and vomiting). Following doses several-fold higher than the therapeutic dose range, seizures and serotonin syndrome have been reported.

Management

Symptomatic treatment and appropriate monitoring. Medical follow-up in a specialised environment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psychoanaleptics; Other antidepressants. ATC code: N06AX26.

Vortioxetine is a multimodal antidepressant. Non-clinical data indicate that vortioxetine is a 5-HT3, 5-HT7 and 5-HT1D receptor antagonist; a 5-HT1B receptor partial agonist; a 5-HT1A receptor agonist; and an inhibitor of the 5-HT transporter (SERT). This multimodal activity leads to modulation of neurotransmission in multiple systems. In PET studies, mean SERT occupancy in the raphe nuclei was approximately 50% at 5 mg/day, 65% at 10 mg/day and >80% at 20 mg/day. Clinical efficacy was established across a programme of >6,700 patients. Vortioxetine demonstrated statistically significant and clinically meaningful reductions in MADRS total score vs placebo at doses of 5, 10 and 20 mg/day. Maintenance of antidepressant efficacy was demonstrated in a relapse-prevention study (time to relapse HR 2.0, vortioxetine superior to placebo, p=0.004). In elderly patients, vortioxetine 5 mg/day was superior to placebo with a 4.7-point MADRS improvement. Vortioxetine also demonstrated significant improvements on cognitive function measures (DSST) and functional capacity (UPSA). In adolescents aged 12–17 years, vortioxetine did not separate from placebo; it should not be used in this age group for MDD.

5.2 Pharmacokinetic properties

Absorption

Slowly but well absorbed after oral administration; peak plasma concentration within 7–11 hours. Absolute bioavailability 75%. No effect of food on pharmacokinetics.

Distribution

Mean volume of distribution (Vss) approximately 2,600 L, indicating extensive extravascular distribution. Plasma protein binding 98–99%.

Biotransformation

Extensively metabolised in the liver, primarily by CYP2D6 (with minor contributions from CYP3A4/5 and CYP2C9) and subsequent glucuronic acid conjugation. The major metabolite is pharmacologically inactive.

Elimination

Mean elimination half-life approximately 66 hours; mean oral clearance 33 L/h. Approximately 2/3 of inactive metabolites excreted in urine; approximately 1/3 in faeces. Steady-state plasma concentrations achieved in approximately 2 weeks. Pharmacokinetics are linear and time-independent over the dose range 2.5–60 mg/day.

Special populations
Elderly (≥65 years): Exposure increased up to 27% (Cmax and AUC) at 10 mg/day vs young healthy subjects. CYP2D6 poor metabolisers: vortioxetine concentrations approximately 2-fold higher than in extensive metabolisers. CYP2D6 ultra-rapid metabolisers: concentrations between those at 5 mg and 10 mg in extensive metabolisers. Renal impairment: modest exposure increases up to 30%; no dose adjustment needed. Hepatic impairment: AUC changes <10% in mild/moderate impairment, 10% higher in severe impairment; no dose adjustment needed.

5.3 Preclinical safety data
CNS-related clinical signs were observed in general toxicity studies in mice, rats and dogs at exposures well above the therapeutic range. Renal changes in rats and hepatic changes in mice and rats were seen at exposures >2- to >10-fold human exposure — mainly attributed to rodent-specific crystalline material obstruction; considered of low risk to humans. Not genotoxic. Not considered carcinogenic. No effect on rat fertility, reproductive organs or sperm. Not teratogenic in rats or rabbits; reproductive toxicity (reduced foetal weight, delayed ossification) observed in rats at exposures >10-fold human exposure; increased pup mortality and delayed development at exposures similar to those in humans at 20 mg/day. Vortioxetine distributed to milk of lactating rats. Environmental risk: may be persistent, bioaccumulative and toxic to fish; however, at recommended patient usage, considered negligible risk to aquatic/terrestrial environment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Microcrystalline cellulose PH 102, mannitol, sodium starch glycolate type 'A', colloidal silicon dioxide, hydroxypropyl cellulose, methanol (manufacturing solvent), dichloromethane (manufacturing solvent), microcrystalline cellulose PH 112, magnesium stearate, purified water (manufacturing solvent). Film coat: Opadry white OY-58900 (hypromellose/HPMC, titanium dioxide, macrogol/PEG).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 Months

6.4 Special precautions for storage
Do not store above 30°C. Protect from moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container
ALU-PVC/PVdC blister. Pack sizes: 10, 30 and 100 tablets

6.6 Special precautions for disposal and other handling
This medicinal product may pose a risk to the environment (see section 5.3). Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
MSN LABORATORIES PRIVATE LIMITED
MSN House, Plot No. C-24, Sanath Nagar Industrial Estate,
Sanathnagar, Hyderabad – 500018, Telangana, India.
Manufacturing site: Formulations Division, Unit-II, Survey Nos. 1277, 1319–1324,
Nandigama (Village & Mandal), Rangareddy District, Telangana – 509228, India.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2026/CTD12092/24163

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

10.04.2026

10. DATE OF REVISION OF THE TEXT

10.04.2026