# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Zopiclone Grindeks 5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg.

Excipients with known effect:

Each 5 mg film-coated tablet contains Cochineal red A (E124) 0.0017 mg.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Blue round biconvex film-coated tablets with plain surfaces; size of tablet is approximately 6 mm in diameter.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Zopiclone is indicated for the short-term treatment of insomnia in adults.

Benzodiazepines and benzodiazepine-like substances are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.

## 4.2 Posology and method of administration

Posology

*Adults*
Prior to starting treatment with zopiclone, a discussion should be held with patients to put in place a strategy for ending treatment with zopiclone in order to minimise the risk of dependence, addiction and drug withdrawal syndrome (see section 4.4).
Treatment should be given for the shortest possible duration. The lowest effective dose should be used.

The usual initial dose is 5 mg as a single dose at bedtime and should not be re-taken during the same night. For patients who do not respond to this dose, the dose can be increased to 7.5 mg.

The dose should not exceed 7.5 mg per day.

Treatment duration
The treatment time should be as short as possible (a few days to 2 weeks) and no longer than 4 weeks, including the tapering off. In some cases, it may be necessary to extend treatment beyond the maximum treatment period; however, this should not take place without re-evaluation of the patient's status since the risk of dependence or abuse increases with dose and duration of treatment (see also section 4.4).

Special populations
*Elderly*
The usual initial dose is 3.75 mg for elderly. The dose may later be increased to 5 mg and, if necessary, up to 7.5 mg.

*Renal impairment*
Although no accumulation of zopiclone or its metabolites have been found in patients with renal insufficiency, it is advisable to begin treatment of patients with reduced renal function at 3.75 mg.

*Hepatic impairment or chronic respiratory failure*
Treatment should be started with a dose of 3.75 mg. The dose may later be increased to 5 mg and, if necessary, up to 7.5 mg.

*Paediatric population*
Zopiclone Grindeks should not be administered in children and adolescents aged less than 18 years. The safety and efficacy of zopiclone in this age group have not been established.

Method of administration
- For oral use.
- The tablet should be taken before bedtime at night.
- The tablets should be taken in an upright position as the absorption might be delayed in the lying position.

## 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Severe hepatic insufficiency
- Sleep apnoea syndrome
- Myasthenia gravis
- Severe respiratory insufficiency
- Previously experienced complex sleep behaviours after taking zopiclone (see section 4.4).

## 4.4 Special warnings and precautions for use

Before starting treatment with zopiclone any underlying cause of insomnia should be addressed carefully.

Zopiclone Grindeks should also be used with caution in patients with a history of alcohol or drug abuse. Concomitant alcohol consumption should be avoided.

Dependence, tolerance and potential for abuse

Drug addiction comprises behavioural, cognitive and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use and possible tolerance or physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, which manifests as withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Addiction and dependence are related but distinct presentations and in discussing these themes, terminology that apportion blame to the individual should be avoided.

For all patients, prolonged use of this product may lead to drug dependence and addiction but can occur with short-term use at recommended therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).

Additional support and monitoring may be necessary when prescribing for patients at risk of drug misuse.

A comprehensive patient history should be taken to document concomitant medications, including over-the-counter medicines and medicines obtained on-line, and past and present medical and psychiatric conditions.

Patients may find that treatment is less effective with chronic use and express a need to increase the dose to obtain the same level of symptom control as

initially experienced. Patients may also supplement their treatment with additional medications to achieve the same effect. These could be signs that the patient is developing tolerance. The risks of developing tolerance should be explained to the patient.
Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else.
Patients should be closely monitored for signs of misuse, abuse, or addiction. The clinical need for treatment with zopiclone should be reviewed regularly, with frequent assessments of patients being undertaken during the course of their treatment.

Drug withdrawal syndrome
Prior to starting treatment with zopiclone, a discussion should be held with patients to explain the risk of dependence, addiction, and drug withdrawal syndrome. A withdrawal strategy for ending treatment with zopiclone should also be put in place with the patient before starting treatment (there may be exceptions to this in specific clinical situations such as symptom management in end of life palliative care).

Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take in excess of weeks or months. Patients should be informed of this when the medication is first prescribed.
The reduction schedule for a patient should be tailored to the individual and should be modified to allow intolerable withdrawal symptoms to improve before making the next reduction. If using a published withdrawal schedule, apply it flexibly to accommodate the person's preferences, changes to their circumstances and the response to dose reductions.

Suggest a slow stepwise rate of reduction proportionate to the existing dose, so that decrements become smaller as the dose is lowered, unless clinical risk is such that rapid withdrawal is needed.

If a patient develops withdrawal reactions, consider pausing the taper or increasing the dosage to the previous tapered dosage level.
If women take this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

Rebound insomnia
A transient syndrome where the symptoms that led to treatment with sedative/hypnotic agents recur in an enhanced form on discontinuation of therapy. The risk of these symptoms occurring is greater with an abrupt discontinuation, especially after prolonged treatment with sleeping pills. Therefore, it is recommended that the patient be informed of this and advised to gradually reduce the dose (see also section 4.8 Undesirable effects). Treatment with sleeping pills should be temporary or intermittent to reduce the risk of withdrawal problems.

Treatment duration
The duration of treatment should be as short as possible (see section 4.2) but not longer than 4 weeks including the tapering off process. This period should only be exceeded after re-evaluation of the patient's status. It may be of benefit to inform the patient at the beginning of treatment that the treatment will be of short duration, and to explain precisely how to reduce the dose gradually.
It is also important to draw attention to the possibility of a rebound effect, so the patient does not worry unduly about these symptoms during the treatment withdrawal.

Psychomotor impairment
Like any other sedative/hypnotic medicine, zopiclone has CNS-depressant effects. Alterations in psychomotor functions are likely to appear within hours of administration. The risk of psychomotor impairment, including the ability to drive, increases in the following situations:
- Taking this medicine less than 12 hours before carrying out an activity requiring alertness (see section 4.7),
- Exceeding the recommended dose,
- Co-administration with other CNS depressants, alcohol, illegal substances or other medicinal products that increase zopiclone blood concentrations (see section 4.5).

Patients should be cautioned against engaging in dangerous activities requiring full alertness or motor coordination (e.g., operating machinery or driving) after taking zopiclone, and especially during the first 12 hours after administration.

Anterograde amnesia
Anterograde amnesia may occur, especially if sleep is interrupted or if bedtime is delayed after taking Zopiclone Grindeks. Anterograde amnesia could appear within hours of administration.
To reduce the risk of anterograde amnesia, the patient should be advised to:
- take the tablet immediately before bedtime or when already in bed,
- create the most favourable conditions for a full night's sleep (7-8 hours).

Somnambulism and associated behaviours
Sleepwalking and other associated complex sleep behaviours such as 'sleep driving', cooking and eating, having sex or making phone calls in sleep, with amnesia for the event, have been reported in patients who have taken the first or any subsequent dose of zopiclone and have not been awaken enough. Patients usually do not remember these events.
Patients can be seriously injured or injure others during complex sleep behaviors. Such injuries may result in a fatal outcome.
The use of alcohol and other CNS depressants with zopiclone may increase the risk of such behaviour or when the maximum recommended dose is exceeded.
Discontinuation of treatment should be strongly considered for patients who reports such behaviour (see section 4.5).

Other psychiatric and paradoxical reactions
Reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychosis, inappropriate behavior and other

behavioral disturbances may occur during treatment with benzodiazepines and benzodiazepine-like agents. In this case, the medicinal product must be discontinued. These reactions occur more often in the elderly.

Suicide / Depression / Major depressive episode
Some epidemiological studies show an increased incidence of suicidal ideation, suicide attempts and suicides in patients with or without depression, and treated with benzodiazepines and other hypnotics, including zopiclone. However, a causal relationship has not been established.

As with other hypnotics, zopiclone does not constitute a treatment for depression and may even mask its symptoms (suicide may be precipitated in such patients).

*In persons with major depressive episode:*
Benzodiazepines and benzodiazepine-like medicinal products should not be prescribed as monotherapy as this may allow the underlying depression to evolve and become persistent, leading to an increased risk of suicide. Because of the suicidal risk in these patients, the lowest possible dose of zopiclone should be used to these patients to avoid the possibility of intentional overdose.

Risks of concomitant use of opioids
Concomitant use of Zopiclone Grindeks and opioids may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as Zopiclone Grindeks with opioids should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Zopiclone Grindeks concomitantly with opioids, the lowest effective dose should be used, and the duration of treatment should be as short as possible (see also general dose recommendation in section 4.2).

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers (where applicable) to be aware of these symptoms (see section 4.5).

Special populations
*Hepatic impairment*
A reduced dosage is recommended, see section 4.2. Benzodiazepines are not indicated to treat patients with severe hepatic insufficiency as they may precipitate encephalopathy (see section 4.3).

*Respiratory impairment*
A lower dose is recommended for patients with chronic respiratory insufficiency due to the risk of respiratory depression.

*Renal impairment*
A reduced dosage is recommended (see sections 4.2).

*Elderly*
Elderly should be given a reduced dose (see section 4.2). There is a risk of fall, particularly in the elderly when they get up during the night due to the muscle relaxing effect of zopiclone.

*Paediatric population*
Zopiclone Grindeks should not be administered in children and adolescents under 18 years of age. The safety and efficacy of zopiclone in this group have not been established.

Excipients
This medicine contains less than 1 mmol (23 mg) sodium per tablet, i.e., is essentially 'sodium-free'.
5 mg film-coated tablet contains Cochineal red A (E124) that may cause allergic reactions.

## 4.5 Interaction with other medicinal products and other forms of interaction

***Concomitant use is not recommended:***

*Alcohol*

Concomitant intake with alcohol is not recommended. The sedative effect of Zopiclone Grindeks can be enhanced when the drug is combined with alcohol. This affects the ability to drive and use machines.

***Interaction has to be taken with caution***

*CNS depressants*

Combination with other CNS depressants, such as neuroleptics, hypnotics, anxiolytics / sedatives, antidepressants, narcotic analgesics, antiepileptics, anaesthetics and sedative antihistamines should be carefully considered as the suppressive effect of zopiclone on the central nervous system may be increased in combination with these agents.

In the case of narcotic analgesics potentiation of euphoria may also occur, which can lead to increased psychological dependence.

*Opioids*

The concomitant use of sedative medicines such as benzodiazepines or related drugs such as Zopiclone Grindeks with opioids increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dosage and duration of concomitant use should be limited (see section 4.4).

*CYP3A4 inhibitors/ CYP3A4 inducers*

Since zopiclone is metabolised via CYP3A4, plasma levels of zopiclone may increase if co-administered with CYP3A4 inhibitors such as macrolide antibiotics, azoles, HIV protease inhibitors and grapefruit juice. The dose reduction of zopiclone may be required during concomitant treatment with CYP3A4 inhibitors.

Conversely, plasma levels of zopiclone may decreased if co-administered with CYP3A4 inducers such as phenobarbital, phenytoin, carbamazepine, rifampicin and products containing St. John's wort. A dose of zopiclone might need to be increased.

*Erythromycin*

The effect of erythromycin on the pharmacokinetics of zopiclone has been studied in healthy subjects. The AUC of zopiclone increases by 80% in the presence of erythromycin, probably due to erythromycin inhibiting the metabolism of drugs metabolised by CYP 3A4. As a consequence, the hypnotic effect of zopiclone may be enhanced.

*Itraconazole*

If co-administered with itraconazole (which inhibits CYP 3A4-mediated metabolism) the bioavailability of zopiclone is increased by approximately 70%.

*Rifampicin*

Rifampicin strongly induces the metabolism of zopiclone likely via CYP 3A4. Its plasma concentration decreases by about 80% and its effects in psychomotor tests are significantly reduced.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

The use of zopiclone is not recommended during pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Zopiclone crosses the placenta.

A large amount of data on pregnant women (more than 1 000 pregnancy outcomes) collected from cohort studies has not demonstrated evidence of the occurrence of malformations following exposure to benzodiazepines or benzodiazepine-like substances during the first trimester of pregnancy. However, certain case-control studies reported an increased incidence of cleft lip and palate associated with use of benzodiazepines during pregnancy.

Cases of reduced fetal movement and fetal heart rate variability have been described after administration of benzodiazepines or benzodiazepine-like substances during the second and/or third trimester of pregnancy.

Administration of benzodiazepines or benzodiazepine-like substances, including zopiclone, during the late phase of pregnancy or during labour have been associated with effects on the neonate, such as hypothermia, hypotonia, feeding difficulties ("floppy infant syndrome"), and respiratory depression, due to the pharmacological action of the product. Cases of severe neonatal respiratory depression have been reported.

Moreover, infants born to mothers who took sedative/hypnotics agents chronically during the latter stages of pregnancy may have developed physical dependence and may be at risk of developing withdrawal symptoms in the postnatal period.

Appropriate monitoring of the newborn in the postnatal period is recommended.

If Zopiclone Grindeks is prescribed to women of childbearing potential, she should be informed to consult a physician to discuss discontinuation of the medicine if she intends to become or suspects that she is pregnant.

Breast-feeding

Zopiclone is excreted in breast milk, although the concentration of zopiclone in the breast milk is low, use in nursing mothers must be avoided.

## 4.7 Effects on ability to drive and use machines

Zopiclone may have a major influence on the ability to drive and use machines.

During treatment with zopiclone, the reactivity may be reduced. This should be considered when alertness is required, e.g., when driving or performing precision work, especially in the first 12 hours following zopiclone administration. To minimise these risks, an uninterrupted rest period of at least 12 hours is recommended between taking zopiclone and driving, using machines or working at heights.

In addition, the risk is increased with concomitant of alcohol intake or other CNS depressants. The risk is even higher when sleep duration is insufficient. Patients should be warned to avoid alcohol or other psychoactive substances when taking zopiclone.

## 4.8 Undesirable effects

Summary of the safety profile

About 10% of treated patients experience some form of side effect. The most common side effect is a bitter taste, often transient, which occurs in about 4% of patients in clinical trials, followed by drowsiness, which is dose dependent.

Tabulated list of adverse reactions

The frequencies of undesirable effects are ranked in the table below according to the following: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data). These effects are related both to the dose taken and the patient's individual sensitivity.

| System organ class | Common | Uncommon | Rare | Very rare | Not known |
|---|---|---|---|---|---|
| Immune system disorders | | | | Angioedema, anaphylactic reactions | |
| Psychiatric disorders | | Agitation, nightmares | Confusional state, libido disorders, irritability, aggression, hallucinations, depression* | | Restlessness, delusions, anger, abnormal behaviour (possibly associated with amnesia) and complex sleep behaviours including somnambulism (see section 4.4), psychosis, physical and psychological dependence |
| Nervous system disorders | Dysgeusia (bitter/metallic taste), drowsiness | Decreased alertness, headache, dizziness | Anterograde amnesia | | Ataxia, paraesthesia, cognitive disorders such as memory impairment, disturbance in attention, speech disorder |
| Eye disorders | | | | | Diplopia |
| Respiratory, thoracic and mediastinal disorders | | | Dyspnoea | | Respiratory depression |
| Gastrointestinal disorders | Dry mouth | Nausea, malaise, abdominal pain | | | Dyspepsia, vomiting |
| Hepatobiliary | | | | Increases in | |

| System organ class | Common | Uncommon | Rare | Very rare | Not known |
|---|---|---|---|---|---|
| disorders | | | | serum transaminases and/or blood alkaline phosphatase (mild or moderate) | |
| Skin and subcutaneous tissue disorders | | | Allergic skin reactions (including rash, itching, urticaria) | | |
| Musculoskeletal and connective tissue disorders | | | | | Muscular weakness |
| General disorders and administration site conditions | | Difficulty getting up in the morning, fatigue (asthenia) | | | Withdrawal syndrome** |
| Injury, poisoning and procedural complications | | | Fall (mainly in the elderly, see section 4.4) | | |

* Existing depression may manifest itself during use of benzodiazepines and benzodiazepine-like substances.
** Use of zopiclone may lead to physical dependence even at therapeutic doses, and discontinuation of treatment may cause withdrawal symptoms or rebound effect (see section 4.4). Psychological dependence may also occur. Abuse has occurred.

Description of selected adverse reactions
*Withdrawal syndrome.*
Withdrawal syndrome has been reported upon discontinuation of zopiclone (see section 4.4). Withdrawal symptoms vary and may include rebound insomnia, muscle pain, anxiety, tremor, sweating, agitation, confusion, headache, palpitations, tachycardia, delirium, nightmares, hallucinations, panic attacks, muscle aches/cramps, gastrointestinal disturbances and irritability. In severe cases the following symptoms may occur: derealisation, depersonalisation, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations. In very rare cases, seizures may occur.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Patients should be informed of the signs and symptoms of overdose and to ensure that family and friends are also aware of these signs and to seek immediate medical help if they occur.

Toxicity
Great individual variations. 5 mg caused mild intoxication in 1½-year-old children. Approximately 30 mg caused moderate intoxication in 6-year-old children. 22.5-50 mg for adults and 40 mg for the elderly caused mild intoxication. >50->100 mg caused mild to moderate intoxication in adults. 100 mg caused deep unconsciousness in adults. 187 mg and alcohol caused severe intoxication for adults.

Symptoms
Overdose is usually manifested by varying degrees of central nervous system depression (in the elderly sometimes very prolonged) ranging from drowsiness to coma. In mild cases, symptoms include fatigue, drowsiness, somnolence, confusion, lethargy, unconsciousness which are sometimes preceded or followed by agitation and hallucinations; in more serious cases, symptoms include ataxia, muscle weakness (hypotonia), hypotension, methaemoglobinaemia, respiratory depression (mainly in combination with alcohol or CNS depressants) and coma.
Other risk factors, such as the presence of concomitant illness or the debilitated condition of the patient, may contribute to the severity of the symptoms and in very rare cases may lead to fatal outcome.

Treatment
Symptomatic and supportive treatment in adequate clinical environment is recommended, attention should be paid to the respiratory and cardiovascular functions. Gastric lavage or activated charcoal is only useful when performed soon after digestion. Flumazenil as an antidote may be useful to relieve CNS and respiratory depression and is mainly indicated in severe poisoning to avoid intubation and respiratory care. Note that the effect duration of flumazenil is shorter than that of zopiclone. Haemodialysis is not useful in treating overdose due to the large volume of distribution of zopiclone.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hypnotics and sedatives; benzodiazepine-related drugs,

ATC code: N05CF01

Zopiclone is a benzodiazepine-like hypnotic agent which belongs to the group of cyclopyrrolones. Its pharmacological properties are: hypnosis, sedation, anxiolysis, anticonvulsion, muscle relaxation. Zopiclone has a high affinity for the binding site within the macromolecular $GABA_A$ receptor complex, where it induces specific conformational changes and enhances the normal transmission of the neurotransmitter GABA in the CNS. Zopiclone has a rapid onset of action (within about 30 minutes), shortens the sleep time, prolongs sleep duration, and reduces the number of awakenings during the night. The amount of REM sleep and deep sleep (stages III and IV) is maintained at the recommended dose.

## 5.2 Pharmacokinetic properties

Absorption

The bioavailability of zopiclone is about 80%. Maximum plasma concentrations are reached within 1.5-2 hours and are approximately 30 ng and 60 ng/ml after a dose of 3.75 mg and 7.5 mg, respectively. The absorption is the same in women and men and is not affected by simultaneous food intake. Absorption may be delayed if zopiclone is ingested horizontally.

Distribution

Zopiclone is rapidly distributed from the vascular compartment. The volume of distribution is 1.3 l/kg and the protein binding levels is about 45% and is not saturable. Less than 1% of the dose ingested by the mother can be expected to reach a breast-feeding infant via breast milk.

Biotransformation

There is no accumulation after repeated administration and inter-individual variations appear to be

minor. Zopiclone is extensively metabolized in the liver by decarboxylation.

About 11% is converted to N-oxide zopiclone, which is less active than the parent substance, and of no clinical significance, and about 15% are transformed into the inactive N-desmethyl-zopiclone. The apparent half-lives are approximately 4.5 and 7.4 hours, respectively.

Elimination

The low renal clearance of zopiclone (mean 8.4 ml/min) compared to plasma clearance (232 ml / minute) indicates that zopiclone is essentially eliminated by metabolism.

The half-life is 5 hours, increased to 7 hours in the elderly. In various trials with elderly patients,

no accumulation of zopiclone was observed in the plasma after repeated doses. Plasma clearance is reduced by approximately 40% in patients with liver cirrhosis, due to the slower methylation process and therefore the dose should be adjusted for these patients. In patients with renal insufficiency, no accumulation of zopiclone, which also crosses the dialysis membrane, or its metabolites has been detected after prolonged administration.

About 80% of all zopiclone is excreted in the urine, mainly in the form of unconjugated metabolites (N-oxide and N-dimethyl derivatives). About 16% is excreted in the faeces.

### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Tablet core

Maize starch

Hypromellose (type 2910) (E464)

Calcium hydrogen phosphate (E341)

Sodium starch glycolate (type A)

Cellulose, microcrystalline (E460)

Magnesium stearate (E572)

Tablet film-coating

Macrogol poly(vinyl alcohol) grafted copolymer (E1209)

Talc (E553b)

Titanium dioxide (E171)

Glycerol monocaprylocaprate (E471)

Poly(vinyl alcohol) (E1203)

Indigo carmine (E132)

Cochineal red A (E124)

Quinoline Yellow (E104)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

10, 20, 30 or 100 film-coated tablets in PVC/PVDC//Alu blisters.
Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

AS GRINDEKS.
Krustpils iela 53
Rīga, LV-1057
Latvia
Phone: +371 67083205

Fax: +371 67083505
E-mail: grindeks@grindeks.com

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25/03/2025

## 10 DATE OF REVISION OF THE TEXT

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