SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OZALIN 2 mg/ml oral solution in single-dose container.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of OZALIN contains 2 mg of midazolam.

Each 5 ml ampoule of OZALIN contains 10 mg of midazolam.

Excipients with known effects: ethanol (less than 100 mg per ampoule), sodium (less than 1 mmol (23 mg) per ampoule), cyclodextrin (400 mg per ampoule and less than the permitted daily exposure of 20 mg/kg/day at the recommended dose).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral solution in single-dose container.

Clear to slightly opalescent solution, pale yellow to slightly brown, with a pH between 3.6 and 4.2.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OZALIN is indicated in infants (from 6 months), children and adolescents, for moderate sedation before a therapeutic or diagnostic procedure to relieve anxiety, distress and agitation related to the procedure or as premedication before anaesthesia.

4.2 Posology and method of administration

OZALIN oral solution should only be administered by healthcare professionals.

General fasting guidelines should be respected before sedation.

Posology

The dose must be adapted to the patient's weight.

OZALIN should be used orally at a single dose of 0.25 mg/kg in paediatric population from the age of six months. An immediate subsequent dose is not recommended (see section 5.2).

The maximum dose should not exceed 20 mg of midazolam (corresponding to 2 ampoules), even for children weighing more than 80 kg.

Ozalin is indicated for single dose administration and there is no data available for repetitive administration of Ozalin.

In obese children the dose should be given according to actual body weight, up to the limit of 20 mg.

The dose must be adapted to the patient's weight. The oral applicator is graduated **in kilograms, from 3 kg to 40 kg body weight (see section 6.6, n°6)**, with three types of graduation marks:

- A small graduation mark corresponding to 1 kg, *i.e.*: 0.25 mg of midazolam,
- An intermediate graduation mark corresponding to 5 kg, *i.e.:* 1.25 mg of midazolam,
- A large graduation mark corresponding to 10 kg, *i.e.:* 2.5 mg of midazolam

For patients above 40 kg, 2 ampoules are needed. The minimal dose to be sampled from an ampoule should correspond to a 3 kg dose. For patients weighing 41 and 42 kg, needing more than one ampoule, take a dose lower than 40 kg in the first ampoule and the supplement to dose in the second ampoule, see examples below:

- For a patient of 41 kg, it is recommended to take 30 kg in the first ampoule and 11 kg in the second ampoule
- For a patient of 42 kg, take a dose corresponding to 30 kg in the first ampoule and 12 kg in the second ampoule.

Special population
Renal impairment
OZALIN should be used with caution in patients with chronic renal failure because elimination of midazolam may be delayed and its effects prolonged.

Hepatic impairment
Hepatic impairment decreases the clearance of midazolam, which increases terminal half-life (for elimination) as well as bioavailability. Careful monitoring of these effects and of vital signs is necessary following the administration of midazolam in these patients (see Section 4.4). OZALIN is contraindicated in patients with severe hepatic impairment (see Section 4.3).

Paediatric population
The safety and efficacy of OZALIN in children under the age of six months have not been established. No data are available.

Method of administration
OZALIN is for oral use only and should be administered with its specific oral applicator graduated in kg.

OZALIN should be administered on average 30 minutes before the procedure or anaesthesia.

The oral applicator and filter straw are single use sampling and administration devices.

After use, the ampoule, the oral applicator and the filter straw should be discarded.

Complete instructions are provided in Section 6.6.

4.3 Contraindications

In patients with:

- hypersensitivity to the active substance, to benzodiazepines or to any of the excipients listed in Section 6.1,
- myasthenia gravis,
- severe respiratory failure,
- an anatomical abnormality of the respiratory tract or lung disease,
- sleep apnoea syndrome,
- severe hepatic impairment.

4.4 Special warnings and precautions for use

Midazolam should be administered only by healthcare professionals in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the recognition and management of expected adverse events including respiratory and cardiac resuscitation. Severe cardiorespiratory adverse events have been reported. These have included respiratory depression, apnoea, respiratory arrest and/or cardiac arrest. Such life-threatening incidents are more likely to occur when given a high dosage.

Administration to high risk patients
Midazolam should be used with caution in patients with chronic respiratory failure because it can exacerbate respiratory depression.

Midazolam should be used with caution in patients with mild or moderate hepatic impairment, heart failure or chronic renal failure. Midazolam or its metabolite may accumulate in patients with chronic renal failure or with liver failure, and the clearance of midazolam may be decreased in patients with heart failure.

Oral midazolam should be used with caution in patients in poor general health as they are more sensitive to the effects of benzodiazepines on the central nervous system.

Modification of midazolam elimination
Oral midazolam should be used with caution in patients treated with medicinal products known to inhibit or induce CYP3A4 (see Section 4.5).

Concomitant use of alcohol/central nervous system depressants
Combined use of midazolam and alcohol and/or central nervous system depressants should be avoided. Such a combination is likely to increase the clinical effects of midazolam, which may cause deep sedation or clinically significant respiratory depression (see Section 4.5).

History of alcoholism or drug addiction
Like other benzodiazepines, midazolam should be avoided in patients with a history of alcoholism or drug addiction.

Amnesia
Midazolam causes anterograde amnesia.

Conditions for discharge
Patients who have received midazolam should be accompanied by an adult upon discharge and leave the treatment room and hospital setting only after complete recovery of the sedative effects and after receiving authorisation from the physician.

Excipients:
At the recommended single dose of 0.25 mg/kg (with a maximum single dose of 20 mg), the amount of gammadex is 10 mg/kg (with a maximum single dose of 800 mg). This amount of gammadex is below the permitted daily exposure (200 mg/kg/day, and 20 mg/kg/day for children younger than 2 years old). Therefore, even if OZALIN would be inadvertently used with 0.5 mg/kg dose, the amount of gammadex would not exceed the permitted daily exposure.
This medicine contains less than 1 mmol (23 mg) of sodium per ampoule, that is to say that this medicine is essentially ‘sodium-free’.
This medicine contains small amounts of ethanol (alcohol), less than 100 mg per ampoule.

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacokinetic drug interactions
Because midazolam is metabolised primarily by CYP3A4 enzyme, CYP3A4 inhibitors and inducers may, respectively, increase or decrease plasma concentrations and hence the clinical effects of midazolam may be increased or reduced and its duration of action prolonged or shortened. Careful monitoring of clinical effects and patient's vital signs is therefore recommended after administering midazolam with a CYP3A4 inhibitor, even after a single dose.

In the case of CYP3A4 inhibition or irreversible inhibition, the effect on the pharmacokinetics of midazolam may persist for several days to several weeks after administration of the CYP3A4 modulator (clarithromycin, erythromycin, HIV protease inhibitors, verapamil, diltiazem, atorvastatin, aprepitant, for example).

During co-administration with ethinylestradiol and norgestrel used as an oral contraceptive, exposure to midazolam is not significantly altered.

CYP3A4 inhibitors:

- Azole antifungals: ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole.
- HIV protease inhibitors: saquinavir and other protease inhibitors, including combinations containing ritonavir.
- Macrolide antibiotics: clarithromycin, erythromycin, telithromycin, roxithromycin; roxithromycin increases the terminal half-life of midazolam administered orally in tablet form by 30%.
- Calcium-channel blockers: diltiazem, verapamil; verapamil and diltiazem multiply the plasma concentrations of oral midazolam by 3 and 4 respectively and increase its terminal half-life by 41% and 49% respectively.
- Substance P antagonists: aprepitant; aprepitant causes a dose-dependent increase in the plasma concentrations of oral midazolam, the plasma concentration is multiplied by 3.3 after 80 mg/day of aprepitant and its terminal half-life by about 2.
- H2-antagonists: cimetidine, ranitidine.
- Selective serotonin reuptake inhibitors: fluvoxamine.
- Anticholinergic drugs: propiverine.
- Other drugs (atorvastatin, nefazodone, aprepitant, ivacaftor).
- Plant products: grapefruit juice, *Echinacea purpurea*, turmeric rhizome.

CYP3A4 inducers:

- Rifamycin antibiotics: rifampicin; rifampicin reduces the plasma concentration of oral midazolam by 96% in healthy subjects with an almost total disappearance of midazolam's psychomotor effects.
- Antiepileptic drugs: carbamazepine, phenytoin; repeated administration of carbamazepine or phenytoin reduces the plasma concentration of oral midazolam by as much as 90% and decreases the terminal half-life by 60%.
- Reverse-transcriptase inhibitors: efavirenz; the ratio of α-hydroxymidazolam (metabolite generated by CYP3A4) is increased by a factor of five compared to midazolam, confirming the induction effect of efavirenz on CYP3A4.
- St. John's wort (*Hypericum perforatum*).

Midazolam is not known to alter the pharmacokinetics of other medicinal products.

Pharmacodynamic drug interactions
Concomitant administration of midazolam with other sedative/hypnotic agents and central nervous system depressants is likely to increase sedation and respiratory depression.

Such sedative/hypnotic agents include alcohol (including medicinal products containing alcohol), opiates/opioids (when used as analgesics, antitussives or substitutive treatments), antipsychotics, other benzodiazepines used as anxiolytics or hypnotics, barbiturates, propofol, ketamine, etomidate, sedative antidepressants, antihistamines, antiepileptics and centrally acting antihypertensives. Midazolam decreases the minimum alveolar concentration (MAC) of inhalation anaesthetics.

The combined effect of alcohol and midazolam should be strictly avoided, and alcohol consumption should be strictly avoided when administering midazolam (see Section 4.4 and Section 4.9).

4.6 Fertility, pregnancy and lactation

Pregnancy

Insufficient data are available on midazolam to assess its safety during pregnancy. Animal studies do not indicate a teratogenic effect, but foetotoxicity was observed as with other benzodiazepines. No data on exposed pregnancies are available for the first two trimesters of pregnancy.

The administration of high doses of midazolam in the last trimester of pregnancy, during labour or when used as an induction agent of anaesthesia for caesarean section has been reported to produce maternal or foetal adverse effects (inhalation risk in mother, irregularities in the fetal heart rate, hypotonia, poor sucking, hypothermia and respiratory depression in the neonate).

Moreover, infants born from mothers who received benzodiazepines chronically during the latter stage of pregnancy may have developed physical dependence and may be at some risk of developing withdrawal symptoms in the postnatal period.

Consequently, midazolam may be used during pregnancy if clearly necessary but it is preferable to avoid using it for caesarean section.
The risk for neonates should be taken into account in case of administration of midazolam for any surgery near the term.

Breastfeeding
Midazolam passes in low quantities into breast milk. Nursing mothers should be advised to discontinue breast-feeding for 24 hours following administration of midazolam.

Fertility
Animal studies have not shown a decrease in fertility (see Section 5.3).

4.7 Effects on ability to drive and use machines

OZALIN has a major influence on the ability to drive and use machines.

Sedation, anterograde amnesia, impaired attention and impaired muscular function can momentarily affect the ability to drive vehicles or use machines. Before administering OZALIN, the patient must be warned not to drive or use a machine until fully recovered. The doctor must decide when these activities may be resumed. It is recommended for the patient to be accompanied by an adult when returning home after discharge.

4.8 Undesirable effects

During the administration of midazolam the following adverse reactions have been reported at an unknown frequency, which cannot be estimated from the available data:

System Organ Class	**Adverse Drug Reaction -** frequency not known
Cardiac disorders	Tachycardia, Bradycardia.

Psychiatric disorders	Paradoxical reactions (agitation, excitation, hallucinations, aggressiveness, disinhibition, dysphoria, adverse behaviour, anxiety), sleep disturbances, involuntary movements, akathisia, walking instability, tremors.
Nervous system disorders	Prolonged/over sedation, drowsiness, somnolence, dizziness, ataxia, vertigo, dysarthria, dry mouth, salivation, enuresis, headache, anterograde amnesia.
Eye disorders	(Generally minor) Blurred vision, diplopia
Respiratory, thoracic and mediastinal disorders	Hypoxemia, transient desaturation, laryngospasm, respiratory depression, airway obstruction, rhonchi / noisy breathing, hiccupping, dyspnoea.
Gastrointestinal disorders	Vomiting, nausea.
Skin and subcutaneous tissue disorders	Pruritus, urticarial reaction, skin rash.
Musculoskeletal and connective tissue disorders	Impaired muscular control.
General disorders and administration site conditions	Unusual fatigue, feeling of weakness.
Immune system disorders	Hypersensitivity, angioedema.

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 reporting system listed in Appendix V.

4.9 Overdose

Symptoms
Like all benzodiazepines, midazolam commonly causes drowsiness, ataxia, dysarthria and nystagmus. Midazolam overdose is rarely life-threatening if the product is taken alone, but an overdose can cause areflexia, apnoea, hypotension, cardiorespiratory depression and in rare cases coma. The respiratory depressant effects of benzodiazepines are more serious in patients with respiratory or heart disease or if the drug is combined with other central nervous system depressants, including alcohol.

Treatment
In most cases, monitoring of vital signs is necessary.

In case of overdose, special attention should be paid to respiratory and cardiovascular functions in intensive care.

In case of overdose, vomiting should be induced (as soon as possible and in any event within an hour of the oral administration of midazolam) if the patient is conscious, or gastric lavage undertaken while protecting the airways if the patient is unconscious. If gastric lavage is not effective, activated charcoal should be administered to reduce absorption.

Flumazenil, a benzodiazepine antagonist, is indicated in case of severe intoxication accompanied by respiratory depression or coma. This treatment should only be administered under close supervision. The half-life of flumazenil is short (about an hour), which means that monitoring is required after the effect of this product has worn off. Extreme caution is required when using flumazenil in case of overdose following a concomitant administration of different drugs in a patient and in patients with epilepsy already treated with benzodiazepines. Flumazenil should only be used with extreme caution in patients treated with

tricyclic antidepressants or epileptogenic drugs and in patients with ECG anomalies (QRS or QT prolongation).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: benzodiazepines, ATC code: N05CD08

Mechanism of action
Midazolam is a derivative of the imidazobenzodiazepine group. The pharmacological effects of benzodiazepines result from reversible interactions with the γ-amino butyric acid (GABA) receptor of the benzodiazepines in the central nervous system, the principal inhibitory neurotransmitter in the central nervous system.

Pharmacodynamic effects
The pharmacodynamic properties of midazolam and its metabolites, which are similar to those of other benzodiazepines, include sedative, anxiolytic, amnesic (anterograde amnesia), hypnotic, muscle relaxant and anticonvulsant effects.

The pharmacological action of midazolam is characterised by a short duration of action due to rapid metabolic transformation. The action of midazolam is easily reversed by the benzodiazepine receptor antagonist: flumazenil.

Clinical efficacy and safety
The data from published reports of studies in paediatric patients clearly demonstrate that oral midazolam acts as a sedative and an anxiolytic prior to a surgical procedure requiring anaesthesia as well as in other medical procedures requiring sedation without anaesthesia.

Several studies have been conducted involving hundreds of children requiring moderate sedation before anaesthetic premedication or medical procedure. These children received a single dose of oral midazolam (without combining another central nervous system depressant drug). Maximum sedation was generally reached within 30 to 45 minutes following administration of midazolam for a dose of midazolam between 0.25 and 1.0 mg/kg. Similar data were obtained for the anxiolytic effect. The sedative effects were obtained for plasma midazolam concentrations between 30 and 160 ng/ml and an EC_{50} ranging between 18 and 171 ng/ml depending on the method used to evaluate sedation (paediatric and adult data).

A study involving OZALIN has been conducted in paediatric patients aged between 6 months and 17 years of age requiring anaesthetic premedication. The findings from this study are consistent with those of the literature. Sedative and anxiolytic effects were observed within 30 minutes following oral administration of a single dose of OZALIN of 0.269 mg/kg on average and a plasma midazolam concentration between 15 and 65 ng/ml. An EC50 of 53.82 ng/ml was observed following oral administration of OZALIN at a dose of 15 mg (0.245 mg/kg on average) in healthy adult subjects. There are no data in non-fasted children and adolescents from 6 months to 17 years old receiving a single oral dose of OZALIN.

5.2 Pharmacokinetic properties

Absorption
Midazolam is absorbed rapidly and completely following oral administration.

Data from literature
The peak plasma concentration (C_{max}) is achieved in 30 to 60 minutes (T_{max}) following oral administration of midazolam. A C_{max} between 70 and 154 ng/ml has been reported after administration of a dose of 15 mg

in healthy adults. A C_{max} ranging from 30 to 200 ng/ml has been reported according to the dose administered (from 0.25 to 1.0 mg/kg) and to the age of the child (from 6 months to 17 years of age).
Bioavailability varies between 30 and 50% depending on the study and the oral formulation used.

Data on OZALIN
After administration of a single dose of OZALIN orally, C_{max} was achieved in 35 to 45 minutes (median T_{max}) in adult and adolescent subjects, respectively. From the population pharmacokinetics (Pop-PK) analysis including adults and paediatric data, most midazolam is absorbed within 30 minutes of administering OZALIN.

Following a 15 mg (0.245 mg/kg on average) oral dose of OZALIN, a C_{max} of 113 ng/ml was obtained in healthy adult subjects. With an OZALIN dose of 0.12 to 0.30 mg/kg, a mean C_{max} of 40.8 ng/ml was reached in children.

The absolute bioavailability of orally administered midazolam is 39.4% in adults who received one 15 mg dose of OZALIN.

Distribution
Tissue distribution of oral midazolam is very rapid and, in most cases, the distribution phase is not apparent or is essentially completed within 1 to 2 hours of oral administration. Midazolam is very lipophilic and extensively distributed. Midazolam is highly bound to plasma proteins (in the region of 96-98%), and primarily to albumin.

The passage of midazolam into the cerebrospinal fluid is slow and insignificant. In humans, midazolam crosses the placental barrier and slowly enters foetal circulation. Small amounts of midazolam are found in breast milk.

Data from literature
The volume of distribution at steady state is between 1.0 and 2.5 l/kg and up to 6.6 l/kg.

Data on OZALIN
The volume of distribution of midazolam is 4.7 l/kg in healthy adult subjects.
From the Pop PK analysis, the central volume of distribution and the peripheral volume of distribution were estimated at 27.9 l at 413 l, respectively, for a typical subject of 34 kg.

Biotransformation
Midazolam is almost completely eliminated by biotransformation. Midazolam is hydroxylated by the CYP3A4 enzyme and the main urinary and plasma metabolite is α-hydroxymidazolam. Plasma concentrations of α-hydroxymidazolam are 30 to 50% of those of the parent molecule. Alpha-hydroxymidazolam is pharmacologically active, and contributes significantly (about 34%) to the effects of oral midazolam.

Data from literature
After oral administration, hepatic first-pass metabolism is estimated at around 30 to 60%.
Following oral administration in children, the ratio of the area under the curve (AUC) of α-hydroxymidazolam to midazolam varies from 0.38 to 0.75.

Data on OZALIN
About 40% of α-hydroxymidazolam exposure is due to the hepatic first-pass effect.

The metabolic ratio is 0.504, 0.364 and 0.313 in children, adolescents and adults respectively.

Elimination
In healthy adult subjects, plasma clearance is between 300 and 500 ml/min (or between 4 and 13 ml/min/kg). Midazolam is eliminated primarily by renal excretion; 60 to 80% of the administered dose is excreted within 24 hours of administration and is recovered in the form of glucuronidated α-hydroxymidazolam. Less than 1% of the administered dose is recovered unchanged in urine. The elimination half-life of midazolam is about 3 hours, and that of α-hydroxymidazolam is approximately 2 hours.

Data from literature
In children, half-life can vary greatly, from 0.5 to 7 hours depending on the study, regardless of the age of the child and the dose of midazolam. Plasma clearance has been estimated at between 1.5 and 3.6 l/h/kg.

Data on OZALIN
Half-life has been estimated at 3.6 hours in adolescents. From, the Pop-PK analysis, the midazolam clearance has been estimated at 34.7 l/h and α-hydroxymidazolam clearance at 40.6 l/h, for a typical subject of 34 kg.

Pharmacokinetics in special populations

New-borns and infants
OZALIN has not been studied in paediatric patients under 6 months of age.

Obese patients
The mean half-life of midazolam is higher in obese patients than in non-obese patients (5.9 hours versus 2.3 hours). This is due to an increase of about 50% in the volume of distribution corrected for total body weight. There is no significant difference in plasma clearance between obese and non-obese subjects. Longer monitoring of obese patients following the procedure may be required.

Patients with hepatic impairment
In patients with cirrhosis, the elimination half-life may be longer and clearance lower than those observed in healthy subjects, due to the risk of α-hydroxymidazolam accumulation (see Sections 4.2 and 4.3).

Patients with renal impairment
The elimination half-life in patients with chronic renal failure is similar to that in healthy subjects. However, oral midazolam should be used with caution in patients with impaired renal function.

Patients with heart failure
The elimination half-life is longer in patients with congestive heart failure than in healthy subjects (see Section 4.4).

5.3 Preclinical safety data

In a rat fertility study, during which the animals received up to ten times the clinical dose, no adverse effects on fertility were observed.

There are no preclinical data of relevance to the prescriber other than those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate, gammadex, sucralose, orange flavour (contains notably 70-80% ethanol), sodium hydroxide (for pH-adjustment), water for injection.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product should not be mixed with other medicinal products.

6.3 Shelf life

Before opening: 36 months.
After opening: the product should be used immediately after opening and then discarded.

6.4 Special precautions for storage

Do not store at temperatures above 25°C.

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

6.5 Nature and contents of container

5 ml amber glass ampoule (type I glass), one filter straw and one oral applicator packaged together into an individual blister.

Box of 1 ampoule, 1 filter straw and 1 oral applicator.
Box of 5 ampoules, 5 filter straws and 5 oral applicators.
Box of 10 ampoules, 10 filter straws and 10 oral applicators.

Oral applicator and filter straw are for single-use. Oral applicator is presented with **graduations in kg of bodyweight: from 3 kg to 40 kg, with increments in one kg.**

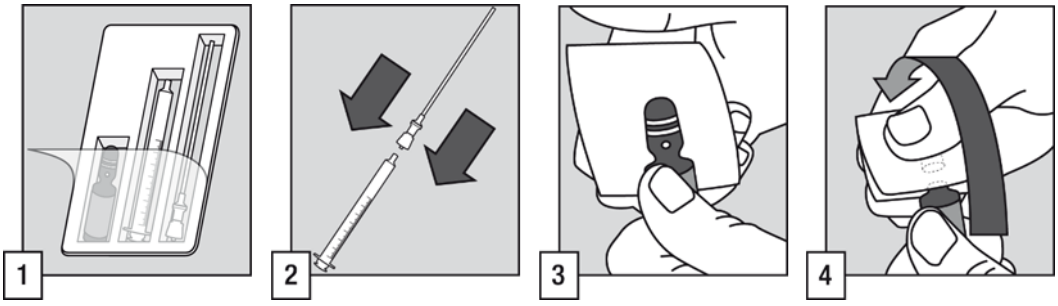
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

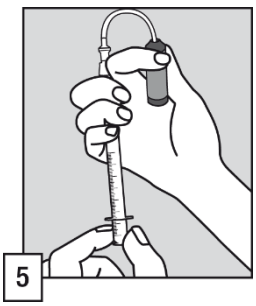
Use in the paediatric population

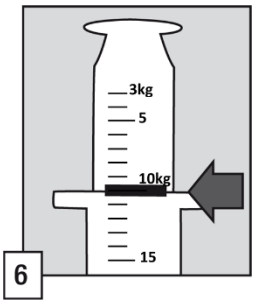
OZALIN is for oral use only.

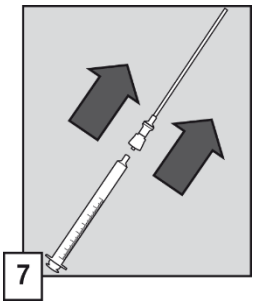
Instruction for safe use of OZALIN ampoule, oral applicator and filter straw provided on the blister. OZALIN should be only administered with its dedicated, specific oral applicator ***graduated in kg*** *:*



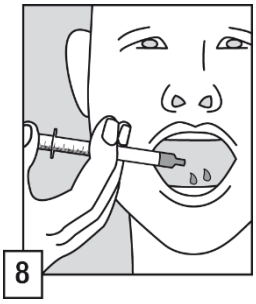
(1) The administration to the patient requires use of the ampoule, the filter straw and the oral applicator.
(2) Connect the filter straw to the end-piece of the oral applicator.
(3) Tap the top of the ampoule to ensure all the liquid has flowed to the bottom. Cover the top of the ampoule with a compress and place the thumb of one hand on the white dot.
(4) Hold the ampoule firmly with the white dot pointing upwards and facing you. Push back on the neck of the ampoule and it will open easily.



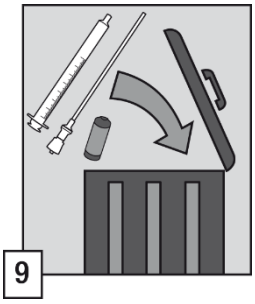




(5) Insert the filter straw into the ampoule. Before adjusting the dosage and in order to eliminate the possible air in the filter straw, a short pumping with the applicator (fill and empty) of the solution inside the ampoule is recommended.
(6) While holding the ampoule in an upright position, fill the oral applicator to the graduation mark corresponding to the **weight of the patient in kilograms (kg)**. Align the line mark with the top of the flange to take the correct dose.
(7) Remove the filter straw from the end piece of the oral applicator.



(8) Empty the contents of the oral applicator into the patient's mouth. The solution should be swallowed immediately.



(9) After use, discard the ampoule, filter straw, oral applicator and any unused contents into a container prepared for this purpose according to the local requirements for controlled substances and pharmaceutical accessories.

7. MARKETING AUTHORISATION HOLDER

PRIMEX PHARMACEUTICALS OY

Mannerheimintie 12 B
00100 Helsinki
FINLAND

DATE OF REVISION OF THE TEXT

14.04.2022