Rewisca
Pregabalin

NAME OF THE MEDICINAL PRODUCT

Rewisca 50 mg hard capsules
Rewisca 75 mg hard capsules
Rewisca 150 mg hard capsules

COMPOSITION

Each hard capsule contains 50 mg, 75 mg or 150 mg pregabalin.

For the full list of excipients, see section List of excipients.

PRODUCT DESCRIPTION

50 mg hard capsules (capsules): The body of the capsule is white colour, the cap of the capsule is bright yellow colour. Capsule cap is imprinted with black mark P50. The content of the capsule is white to off white powder. Capsule size No. 3.
75 mg hard capsules: The body of the capsule is brownish yellow colour, the cap of the capsule is brownish yellow colour. Capsule cap is imprinted with black mark P75. The content of the capsule is white to off white powder. Capsule size No. 4.
150 mg hard capsules: The body of the capsule is white colour, the cap of the capsule is yellowish brown colour. Capsule cap is imprinted with black mark P150. The content of the capsule is white to off white powder. Capsule size No. 2.

THERAPEUTIC INDICATIONS

Neuropathic pain
Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy
Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised Anxiety Disorder
Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Fibromyalgia
Pregabalin is indicated for the treatment of fibromyalgia.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology
The dose range is 150 to 600 mg per day given in either two or three divided doses.

Neuropathic pain
Pregabalin treatment can be started at a dose of 150 mg per day. Based on individual patient response

and tolerability, the dose may be increased to 300 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval.

Fibromyalgia
The usual dose range for most patients is 300 to 450 mg per day given in two divided doses. Some patients may derive additional benefit at 600 mg per day. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within one week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day). If needed, in some patients, based on individual response and tolerability, the dose may be increased to maximum dose of 600 mg/day after an additional week.

Epilepsy
Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. The maximum dose of 600 mg per day may be achieved after an additional week.

Generalised Anxiety Disorder
The dose range is 150 to 600 mg per day given as two or three divided doses. The need for treatment should be reassessed regularly. Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. Following an additional week the dose may be increased to 450 mg per day. The maximum dose of 600 mg per day may be achieved after an additional week.

Discontinuation of pregabalin
If pregabalin has to be discontinued, it is recommended this should be done gradually over a minimum of 1 week.

Patients with renal impairment
Dose reduction in patients with compromised renal function must be individualised according to creatinine clearance (CLcr) (sees section Pharmacokinetic properties), as indicated in Table 1 determined using the following formula:

$$\mathrm{CLcr(ml/min)} = \left[\frac{140 - \text{age (years)} \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}}\right] \text{(x 0.85 for female patients)}$$

For patients receiving haemodialysis, the pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4 hour haemodialysis treatment (see Table 1).

Table 1. Pregabalin dose adjustment based on renal function

Creatinine clearance (CLcr) (ml/min)	Total pregabalin daily dose *		Dose regimen
	Starting dose (mg/day)	Maximum dose (mg/day)	
≥ 60	150	600	BID or TID
≥30 - <60	75	300	BID or TID
≥15 - <30	25 – 50	150	Once daily or BID
<15	25	75	Once daily
Supplementary dosage following haemodialysis (mg)			
	25	100	Single dose+

TID = Three divided doses
BID = Two divided doses
* Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose
+ Supplementary dose is a single additional dose

Patients with hepatic impairment
No dose adjustment is required for patients with hepatic impairment (see section Pharmacokinetic properties).

Paediatric population (12 to 17 years of age)
The safety and efficacy of pregabalin in children below the age of 12 years and in adolescents (12-17 years of age) have not been established. The use in children is not recommended.

Use in the elderly (over 65 years of age)
Elderly patients may require a dose reduction of pregabalin due to a decreased renal function (see Patients with renal impairment and section Pharmacokinetic properties).

Method of administration
Rewisca may be taken with or without food.
Rewisca is for oral use only.

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Angioedema
There have been post-marketing reports of angioedema in patients during initial and chronic treatment with pregabalin. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. Discontinue pregabalin immediately in patients with these symptoms.
Exercise caution when prescribing pregabalin to patients who have had a previous episode of angioedema. In addition, patients who are taking other drugs associated with angioedema [e.g., angiotensin converting enzyme inhibitors (ACE-inhibitors)] may be at increased risk of developing angioedema.

Hypersensitivity reactions
There have been reports in the postmarketing experience of hypersensitivity reactions in patients shortly after initiation of treatment with pregabalin. Adverse reactions included skin redness, blisters, hives, rash, dyspnea and wheezing. Discontinue pregabalin immediately in patients with these symptoms.

Withdrawal of antiepileptic medicinal products (AEDs)
As with all AEDs, withdraw pregabalin gradually to minimize the potential of increased seizure frequency in patients with seizure disorders. If pregabalin is discontinued, taper the medicinal product gradually over a minimum of 1 week.

Suicidal behaviour and ideation
AEDs, including pregabalin, increase the risk of suicidal thoughts or behaviour in patients taking these medicinal products for any indication. Monitor patients treated with and AED for any indication for the emergence or worsening of depression, suicidal thoughts or behaviour, and/or unusual changes in

mood or behaviour.
The increased risk of suicidal thoughts or behaviour with AEDs was observed as early as one week after starting treatment with AEDs and persisted for the duration of the treatment assessed (risk of suicidal thoughts or behaviour was not assessed beyond 24 weeks of treatment).
The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years).

Anyone considering prescribing pregabalin or any other AED must balance the risk of suicidal thoughts or behaviour with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behaviour. Should suicidal thoughts and behaviour emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patients may be related to the illness being treated.
Inform patients, their caregivers and families that pregabalin and other AEDs increase the risk of suicidal thoughts and behaviour and advise them of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behaviour or the emergence of suicidal thoughts, behaviour or thoughts about self-harm. Report behaviours of concern immediately to the healthcare providers.

Peripheral edema
Pregabalin treatment may cause peripheral edema. Peripheral edema was not associated with laboratory changes suggestive of deterioration in renal or hepatic function nor with cardiovascular complications such as hypertension or congestive heart failure.
Higher frequencies of weight gain and peripheral edema were observed in patients taking both pregabalin and thiazolidinedione antidiabetic agent compared to taking either medicinal product alone. As the thiazolidindione class of antidiabetic medicinal products can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, exercise caution when co-administering pregabalin and these agents.
Although there has been no causal relationship identified between exposure to pregabalin and congestive heart failure, there has been post-marketing reports on congestive heart failure in some patients receiving pregabalin. Because there are limited data on congestive heart failure patients with New York Heart Association (NYHA) class III or IV cardiac status, exercise caution when using pregabalin in these patients.

Dizziness, somnolence
Pregabalin may cause dizziness and somnolence. Inform patients that pregabalin-related dizziness and somnolence may impair their ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population.
Loss of consciousness, confusion and mental impairment have been reported. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medication.
Pregabalin in not known to be active at receptor sites associated with drug abuse. Cases of abuse have been reported. As with any CNS active drug, carefully evaluate patients for history of drug abuse and observe them for signs of pregabalin abuse.

Weight gain
Pregabalin treatment may cause weight gain. Pregabalin associated weight gain is related to dose and duration of treatment, but is not associated with baseline BMI, gender or age. Weight gain is also not limited to patients with edema. The long-term cardiovascular effects of pregabalin-associated weight gain are not known. The effects of pregabalin-associated weight gain on glycemic control have not been systematically assessed. Some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medications.

Abrupt or rapid discontinuation
After discontinuation of short-term and long-term treatment with pregabalin withdrawal symptoms have been observed in some patients. The following events have been mentioned: insomnia, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, hyperhidrosis and dizziness, suggestive of physical dependence. The patient should be informed about this at the start of the treatment.

Convulsions, including status epilepticus and grand mal convulsions, may occur during pregabalin use or shortly after discontinuing pregabalin.

Concerning discontinuation of long-term treatment of pregabalin, there are no data of the incidence and severity of withdrawal symptoms in relation to duration of use and dose of pregabalin.

Ophthalmological effects
A higher proportion of patients treated with pregabalin reported blurred vision which resolved in a majority of cases with continued dosing. Although the clinical significance of the ophthalmologic findings is unknown, inform patients to notify their physician if changes in vision occur. If visual disturbance persist, consider further assessment. Consider more frequent assessment of patients who are already routinely monitored for ocular conditions.
Visual adverse reactions have also been reported, including loss of vision, visual blurring or other changes of visual acuity, many of which were transient. Discontinuation of pregabalin may result in resolution or improvement of these visual symptoms.

Creatine kinase elevations
Pregabalin treatment was associated with creatine kinase elevations. Instruct patients to promptly report unexplained muscle pain, tenderness or weakness particularly if these muscle symptoms are accompanied by malaise or fever. Discontinue treatment with pregabalin if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

Decreased platelet count
Pregabalin treatment was associated with a decrease in platelet count.

PR interval prolongation
Pregabalin treatment was associated with PR interval prolongation. In analyses of ECG data the mean PR interval increase was 3-6msec at pregabalin doses ≥300 mg/day. This mean change difference was not associated with an increased risk of PR increase ≥25% from baseline, in increased percentage of subject with on-treatment PR >200 msec, or an increased risk of adverse reactions of second or third degree AV block.

Others
Although the effects of discontinuation on the reversibility of renal failure have not been systematically studied, improved renal failure following discontinuation or dose reduction of pregabalin has been reported.

Abuse potential
Cases of abuse have been reported. Caution should be exercised in patients with history of substance abuse and the patient should be monitored for symptoms of pregabalin abuse.

Encephalopathy
Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate encephalopathy.

Treatment of central neuropathic pain due to spinal cord injury
In the treatment of central neuropathic pain due to spinal cord injury the incidence of adverse reactions in general, central nervous system adverse reactions and especially somnolence was increased. This may be attributed to an additive effect due to concomitant medicinal products (e.g. anti-spasticity agents) needed for this condition. This should be considered when prescribing pregabalin in this condition.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Since pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism *in vitro*, and is not bound to plasma proteins, it is unlikely to produce, or be subject to, pharmacokinetic interactions.

No clinically relevant pharmacokinetic interactions were observed between pregabalin and phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. Population pharmacokinetic analysis indicated that oral antidiabetics, diuretics, insulin, phenobarbital, tiagabine and topiramate had no clinically significant effect on pregabalin clearance.

Co-administration of pregabalin with the oral contraceptives norethisterone and/or ethinyl oestradiol does not influence the steady-state pharmacokinetics of either substance.

Pregabalin may potentiate the effects of ethanol and lorazepam. In the postmarketing experience, there are reports of respiratory failure and coma in patients taking pregabalin and other central nervous system (CNS) depressant medicinal products. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone.

There are reports of events related to reduced lower gastrointestinal tract function (e.g. inteastinal obstruction, paralytic ileus, constipation) when pregabalin was co-administered with medicinal products that have the potential to produce constipation such as opioid analgesics.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy
There are no adequate data from the use of pregabalin in pregnant women.
Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown.

Pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus. Effective contraception must be used in women of child bearing potential.

Breast-feeding
Pregabalin is excreted in human milk. The effect of pregabalin on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue pregabalin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Pregabalin may have minor or moderate influence on the ability to drive and use machines.
Pregabalin may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform

these activities.

UNDESIRABLE EFFECTS

Summary of the safety profile
The most commonly reported adverse reactions were dizziness and somnolence. Adverse reactions were usually mild to moderate in intensity.

The adverse reactions listed may also be associated with the underlying disease and/or concomitant medications.

System organ class	Adverse drug reactions
Infections and infestations	
Common	Nasopharyngitis
Blood and lymphatic system disorders	
Uncommon	Neutropaenia
Metabolism and nutrition disorders	
Common	Appetite increased
Uncommon	Anorexia, hypoglycaemia
Psychiatric disorders	
Common	Euphoric mood, confusion, irritability, depression, disorientation, insomnia, libido decreased
Uncommon	Hallucination, restlessness, agitation, depressed mood, elevated mood, mood swings, depersonalisation, abnormal dreams, word finding difficulty, libido increased, anorgasmia,
Rare	Panic attack, disinhibition, apathy
Nervous system disorders	
Very common	Dizziness, somnolence
Common	Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoesthesia, sedation, balance disorder, lethargy
Uncommon	Syncope, myoclonus, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, speech disorder, hyporeflexia, hyperaesthesia, burning sensation,
Rare	Stupor, parosmia, hypokinesia, ageusia, dysgraphia
Eye disorders	
Common	Vision blurred, diplopia
Uncommon	Peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, photopsia, dry eye, lacrimation increased, eye irritation
Rare	Oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness
Ear and labyrinth disorders	
Common	Vertigo
Uncommon	Hyperacusis
Cardiac disorders	
Uncommon	Tachycardia, atrioventricular block first degree, sinus bradycardia
Rare	Sinus tachycardia, sinus arrhythmia
Vascular disorders	
Uncommon	Hypotension, hypertension, hot flushes, flushing, peripheral coldness
Respiratory, thoracic and mediastinal disorders	
Uncommon	Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring,
Rare	Throat tightness, nasal dryness

System organ class	Adverse drug reactions
Gastrointestinal disorders	
Common	Vomiting, constipation, flatulence, abdominal distension, dry mouth
Uncommon	Gastrooesophageal reflux disease, salivary hypersecretion, hypoaesthesia oral
Rare	Ascites, pancreatitis, dysphagia
Skin and subcutaneous tissue disorders	
Uncommon	Rash popular, urticaria, sweating,
Rare	Cold sweat
Musculoskeletal and connective tissue disorders	
Common	Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm,
Uncommon	Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness
Rare	Rhabdomyolysis
Renal and urinary disorders	
Uncommon	Urinary incontinence, dysuria
Rare	Renal failure, oliguria
Reproductive system and breast disorders	
Uncommon	Erectile dysfunction, sexual dysfunction, ejaculation delayed, dysmenorrhoea
Rare	Breast pain, amenorrhoea, breast discharge, breast enlargement
General disorders and administration site conditions	
Common	Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue
Uncommon	Generalised oedema, chest tightness, pain, pyrexia, thirst, chills, asthenia
Investigations	
Common	Weight increased
Uncommon	Blood creatine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood glucose increased, platelet count decreased, blood potassium decreased, weight decreased
Rare	White blood cell count decreased, blood creatinine increased

The following adverse events were reported during post-marketing surveillance:
Immune system disorders: Uncommon: Hypersensitivity: Rare: Angioedema, allergic reaction.
Nervous system disorders: Very common: Headache; Uncommon: Loss of consciousness, mental impairment.
Eye disorders: Rare: Keratitis*.
Cardiac disorders: Rare: Congestive heart failure.
Respiratory and thoracic disorders: Rare: Pulmonary oedema*.
Gastrointestinal disorders: Common: nausea, diarrhea; Rare: Swollen tongue.
Skin and subcutaneous tissue disorders: Uncommon: Face swelling, pruritus.
Renal and urinary disorders: Rare: Urinary retention.
Reproductive system and breast tissue disorders: Rare: Gynecomastia*.
General disorders and administration site conditions: Uncommon: Malaise.
* Adverse drug raction frequency estimated using ″The Rule of 3″.

OVERDOSE

In overdoses up to 15 g, no unexpected adverse reactions were reported.
The most commonly reported adverse events observed when pregabalin was taken in overdose included affective disorder, somnolence, confusional state, depression, agitation, and restlessness.

Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary (see section Posology and method of administration Table 1).

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiepileptics, other antiepileptics; ATC code: N03AX16.

The active substance, pregabalin, is a gamma-aminobutyric acid analogue [(S)-3-(aminomethyl)-5-methylhexanoic acid].

Mechanism of action
Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

Evidence from animal models with nerve damage has shown that pregabalin reduces calcium dependent release of pro-nociceptive neurotransmitters in the spinal cord possibly by disrupting calcium trafficking and/or reducing calcium currents. Evidence from other animal models of nerve damage suggests the antinociceptive activities of pregabalin may also be mediated through interactions with the descending noradrenergic and serotonergic pathways.

PHARMACOKINETIC PROPERTIES

Pregabalin steady-state pharmacokinetics are similar in all patient groups.

Absorption
Pregabalin is rapidly absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥90% and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in C_{max} by approximately 25-30% and a delay in t_{max} to approximately 2.5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution
Pregabalin has been shown to cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. In humans, the apparent volume of distribution of pregabalin following oral administration is approximately 0.56 l/kg. Pregabalin is not bound to plasma proteins.

Biotransformation
Pregabalin undergoes negligible metabolism in humans. Following a dose of radiolabelled pregabalin, approximately 98% of the radioactivity recovered in the urine was unchanged pregabalin. The N-methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0.9% of the dose. There was no indication of racemisation of pregabalin S-enantiomer to the R-enantiomer.

Elimination
Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Pregabalin mean elimination half-life is 6.3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance (see section Pharmacokinetic properties - Renal impairment). Dose adjustment in patients with reduced renal function or undergoing haemodialysis is necessary (see section Posology and method of administration Table 1).

Linearity/non-linearity
Pregabalin pharmacokinetics are linear over the recommended daily dose range. Inter-subject pharmacokinetic variability for pregabalin is low (<20%). Multiple dose pharmacokinetics are

predictable from single-dose data. Therefore, there is no need for routine monitoring of plasma concentrations of pregabalin.

Pharmacokinetics in special patient groups
Gender
Gender does not have a clinically significant influence on the plasma concentrations of pregabalin.

Renal impairment
Pregabalin clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by haemodialysis (following a 4 hour haemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Because renal elimination is the major elimination pathway, dose reduction in patients with renal impairment and dose supplementation following haemodialysis is necessary (see section Posology and method of administration Table 1).

Hepatic impairment
Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged drug in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Older people (over 65 years of age)
Pregabalin clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age related compromised renal function (see section Posology and method of administration, Table 1).

LIST OF EXCIPIENTS

Capsule contents:
Pregelatinised starch, talc (E553b)

Capsule shell:
50 mg and 75 mg hard capsule: titanium dioxide (E171), gelatin, yellow iron oxide (E172), black printing ink (shellac, black iron oxide (E172), propylene glycol)
150 mg hard capsules: titanium dioxide (E171), gelatin (E441), red iron oxide (E172), yellow iron oxide (E172), black printing ink (shellac, black iron oxide (E172), propylene glycol)

SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 30 °C.

PRESENTATION

Blister: 60 hard capsules, in a box.
Each blister contents 10 capsules.

SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

PRODUCT REGISTRATION HOLDER

PAHANG PHARMACY SDN. BHD.

1.3.1	Pregabalin
SPC, Labeling and Package Leaflet	MY

Lot 5979, Jalan Teratai, 5 ½ Miles, Off Jalan Meru, 41050 Klang, Selangor, Malaysia

NAME AND ADDRESS OF THE MANUFACTURER

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

DATE OF REVISION OF THE TEXT