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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Miln-Avnir 25 mg
Miln-Avnir 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 25 mg of milnacipran hydrochloride (equivalent to 21.77 mg milnacipran) or 50 mg of milnacipran hydrochloride (equivalent to 43.55 mg milnacipran).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard.

Miln-Avnir 25 mg capsules: Caramel opaque capsules, size 4 containing white or almost white powder.
Miln-Avnir 50 mg capsules: Red caramel opaque capsules, size 3 containing white or almost white powder.

4. CLINICAL PARTICULARS

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 25; there was a reduction in risk with antidepressant use in patients aged 65 and older [see Special warnings and precautions for use (4.5)].
In patients of all ages who are started on antidepressant therapy monitor closely for clinical worsening and emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber [see Special warnings and precautions for use (4.5)].

4.1 Therapeutic indications

Treatment of major (i.e. all characteristics) depressive episodes in adults over 18 years old.

4.2 Posology and method of administration

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Oral use.

Adults
Recommended daily dose is 100 mg divided into two 50 mg doses, 1 capsule in the morning and 1 capsule in the evening, preferably during meals.
In this case, use 50 mg capsules.

Special populations
Elderly: dosage adjustment is not necessary as long as renal function is normal (see section 5.2).
Patients with renal insufficiency: dosage adjustment is necessary. It is recommended to reduce the dose to 50 or 25 mg depending on the degree of alteration in renal function (see section 5.2). In this case, use 25 mg capsules.
The following dose adjustment is recommended:

Creatinine clearance (CrCl) (ml/min)	**Posology / 24 h**
CrCl > 60	50 mg x 2
60 > CrCl ≥ 30	25 mg x 2
30 > CrCl ≥ 10	25 mg

Duration of treatment
Treatment with antidepressants is symptomatic.
As with any antidepressants, the efficacy of milnacipran only becomes apparent after a certain delay which can vary from 1 to 3 weeks.
For one episode treatment should last for several months (usually about 6 months) in order to prevent relapses.
Treatment with Milnacipran should be discontinued gradually.

Associated psychotropic treatments
Concomitant prescription of a sedative or anxiolytic treatment can be useful at the start of treatment to prevent occurrence or worsening of manifestations of anxiety.
But anxiolytics do not necessarily protect the patient from suicide attempts.

4.3 Contraindications

This medicine MUST NEVER BE USED in the following cases:

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- association with irreversible MAO inhibitors, B selective MAO inhibitors, digitalis and 5HT1D agonists (sumatriptan, etc.) (see section 4.5)
- lactation;
- uncontrolled hypertension, severe or unstable coronary heart disease as these underlying conditions may be compromised by increases in blood pressure or heart rate.

Generally, this medication should not be used in the following cases:
- In association with epinephrine and norepinephrine by parenteral route, clonidine and

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related compounds and A selective MAO inhibitors (see section 4.5)
- Prostatic hypertrophy and other genito-urinary disorders

4.4 Special warnings and precautions for use

Sexual dysfunction
Selective serotonin reuptake inhibitors (SSRIs)/serotonin norepinephrine reuptake inhibitors (SNRIs) may cause symptoms of sexual dysfunction (see section 4.8). There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs/SNRI.

Suicide/suicidal thoughts or clinical worsening
Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.
Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.
A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old.
Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

Paediatric population
Use in children and adolescents under 18 years of age
Milnacipran should not be used in the treatment of children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with a placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.

Serotonin syndrome
As with other serotoninergic agents, the development of a potentially life-threatening serotonin syndrome may occur with milnacipran treatment, particularly with concomitant use of other medicines that may affect the serotonergic neurotransmitter system (as irreversible MAO inhibitors (iproniazide), A selective MAO inhibitors (linezolid, moclobemide methylene blue), St. John's Wort [Hypericum perforatum], pethidine, tramadol, most of the antidepressant (see sections 4.3 and 4.5)).

Serotonin syndrome symptoms may include:
- Digestive symptoms (diarrhoea),
- Changes in psychiatric status and behaviour (agitation, confusion, hypomania),

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- Motor dysfunction (tremor, rigidity, myoclonus, hyperreflexia and ataxia),
- Autonomic instability (labile blood pressure, tachycardia, shivering, hyperthermia, possibly coma).

The concomitant use of milnacipran with alpha and beta sympathomimetics (IM and IV routes) is not recommended.

Precautions for Use

Patients with insomnia or nervousness at the beginning of treatment may require transient symptomatic therapy.

If a patient experiences a switch into frank mania, treatment with Milnacipran should be discontinued and in most cases a sedative antipsychotic agent prescribed.
Miln-Avnir should be discontinued in patients who develop jaundice or other evidence of liver dysfunction. Treatment with Miln-Avnir should not be resumed unless another cause can be established. Although no interaction with alcohol has been evidenced, it is recommended to avoid alcohol intake, just as with any psychotropic medication.
Systemic body exposure to Milnacipran is increased by 20% when combined with levomepromazine, in healthy volunteers. A higher increase may be suspected in elderly or renal impairment patients if the drugs are to be combined.

Milnacipran should be prescribed with caution in the following cases:

- in patients with renal failure:
  Dosage may have to be reduced because of prolongation of elimination half-life (see section 4.2);
- in patients with a history of difficult passage of urine, notably in patients with prostatic hypertrophy and other genito-urinary disorders. Because of the noradrenergic component of the mechanism of Milnacipran action, a monitoring of the miction disorders is necessary;
- in patients with hypertension or cardiac disease*:*
  Blood pressure and heart rate monitoring is recommended at treatment initiation, following dosage increases and periodically throughout the treatment with milnacipran for all patients and more closely in patients with known cardiovascular risk. In case of sustained elevated blood pressure or elevated heart rate, discontinuation of the treatment with milnacipran should be considered if clinically warranted.
- in patients with high intra-ocular pressure or at risk of narrow-angle glaucoma;
- in patients with epilepsy or with a history of epilepsy: Milnacipran should be used with caution and should be discontinued in any patient developing a seizure.

There have been cases of hyponatraemia in patients receiving serotonin re-uptake inhibitors, possibly due to the syndrome of inappropriate antidiuretic hormone secretion. Caution is advised in elderly, patients taking diuretics or other treatment known to induce hyponatremia, patients with cirrhosis or malnutrition.
Cases of haemorrhages, sometimes serious, have been reported with the use of serotonin re-uptake inhibitors. SSRIs/SNRIs may increase the risk of postpartum haemorrhage (see sections 4.6, 4.8).
Caution should be exercised in patients concomitantly treated with oral anticoagulants, drugs which have an effect on platelet function, e.g. NSAIDs and aspirin, or other drugs that may increase the risk of bleeding. Caution is also required in patients with previous bleeding

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abnormalities.

The safety and efficacy of milnacipran for treatment of major depressive episodes in adults in higher dosage than 100 mg per day have not been established. For patients who do not experience clinical benefit with 100 mg per day, the treatment should be discontinued.

Discontinuation of treatment
The risk of withdrawal reactions seen with SSRI's and SNRI's may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction.
Generally, the symptoms are mild to moderate; however, in some patients, they may be severe in intensity. They usually occur within the first few days of discontinuing treatment but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally, these symptoms are self-limiting and resolve within two weeks, though in some individuals they may be prolonged (2-3 months or more).

It is therefore advised that milnacipran should be gradually tapered when discontinuing treatment and not abruptly discontinued after extended use (see section 4.2 and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have only been performed in adults.
COMBINATIONS CONTRA-INDICATED:
With irreversible MAO inhibitors (iproniazid)
Risk of a serotonin syndrome (see section 4.4).
There should be an interval of two weeks between the end of treatment with a MAO inhibitor and the beginning of treatment with Milnacipran, and at least one week between the end of treatment with Milnacipran and the beginning of treatment with the MAO inhibitor.

Strict compliance with the dosage prescribed is an essential factor in preventing the onset of this syndrome.

With B Selective MAO inhibitors *(selegiline)*
Risk of paroxystic hypertension.
There should be an interval of two weeks between the end of treatment with a B selective-MAO inhibitor and the beginning of treatment with Milnacipran and at least one week between the end of treatment with Milnacipran and the beginning of treatment with B-MAO inhibitor.

With 5 HT1D agonists *(sumatriptan, etc.)*
By extrapolation with selective inhibitors of serotonin re-uptake.
Risk of hypertension and coronary artery vasoconstriction by additive serotoninergic effects.
Wait one week between the end of treatment with Milnacipran and the beginning of treatment with 5HT1D agonists.

With Digitalis *(digoxin, etc.)*
Risk of increased haemodynamic effects, in particular by parenteral route.

With alpha and beta sympathomimetics (*IM and IV routes*)

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Paroxystic hypertension with possible arrhythmia (inhibition of entry epinephrine or norepinephrine into the sympathetic nerve fiber).

With Clonidine and related compounds
Inhibition of clonidine's antihypertensive effect (antagonism with adrenergic receptors).

With A selective MAO inhibitors (linezolid, moclobemide, toloxatone, methylene blue)
Risk of development of serotoninergic syndrome* (see section 4.4)
If this combination cannot be avoided, monitor patient very carefully. Initiate such a combination with the lowest recommended dose.

Adrenalin (***gingival and subcutaneous routes***)
Serious disorder of ventricular rhythm by increase of cardiac excitability.
Limit intake, for example, to less than 0.1 mg of adrenalin in 10 minutes or 0.3 mg in an hour, in adults.

ASSOCIATIONS REQUIRING PRECAUTIONS FOR USE:

With oral anticoagulants
Drugs which have an effect on platelet function, e.g. NSAIDs and aspirin, or other drugs that may increase the risk of bleeding

With Diuretics
Risk of hyponatraemia (see section 4.4)

Lithium
Risk of onset of *serotonin syndrome** (see section 4.4). Perform regular clinical monitoring of the patient.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of Milnacipran in pregnant women.
Animal studies have shown reproductive toxicity (see section 5.3). Neonatal risk after pregnancy exposure with serotonin re-uptake inhibitors have been reported and may be related to either withdrawal syndrome or serotonin toxicity: tachypnea, feeding difficulties, tremors, hypertonicity or hypotonia, sleeping disorders, hyperexcitability or more rarely long- lasting crying. All these signs appear in the first days of life and are generally of short duration and not severe.

Consequently, as a precautionary measure, it is preferable to avoid Milnacipran during pregnancy and in women of childbearing potential not using contraception.

Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth (see sections 4.4, 4.8).

Breast-feeding

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Because small amounts of Milnacipran are excreted in breast-milk, breast-feeding is contraindicated.

Fertility
Milnacipran affected fertility in rats and induced embryolethality with no safety margin (see section 5.3).
No human data on the effect of active substance Milnacipran on fertility are available.

4.7 Effects on ability to drive and use machines

Although no alteration in cognitive or psychomotor functions has been observed in healthy volunteers, this medication can reduce mental and physical capacities necessary to perform certain dangerous tasks, such as operating machinery or driving motor vehicles.

4.8 Undesirable effects

The undesirable effects observed during treatment with Milnacipran in depression indication are observed mainly during the first week or first two weeks of treatment and subsequently regress, concomitantly with improvement in the depressive episode.
The following table gives the adverse events for which a causality assessment was not 'excluded', observed in 13 clinical studies, including 5 placebo-controlled clinical trials (comprising a total of 3,059 subjects - 2,557 on milnacipran and 502 on placebo) in depressive patients.
The most commonly reported adverse drug reactions in depressive patients treated with Milnacipran in the clinical trials were nausea, and headaches.

Table of adverse reactions for depression

Frequency estimate:
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), not known (cannot be estimated from the available data). No adverse drug reaction are 'very rare' in frequency and therefore the column 'very rare' is not represented in the table.

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)	Not known
Blood and lymphatic system disorders				
				Ecchymosis(1)(3) Cutaneous or mucous bleedings(1)(3)
Immune system disorders				
		Hypersensitivity	Anaphylactic shock	
Endocrine disorders				
			Inappropriate antidiuretic hormone secretion	
Metabolism and nutrition disorders				
		Hyperlipidaemia Weight decreased		hyponatremia(1)(3)
Psychiatric disorders				

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	Agitation Anxiety Depression Eating disorders Sleep disorders Suicidal behaviour	Panic attack Confusional state Delusion Hallucinations. Mania Libido decreased Nightmare Suicidal ideation	Derealization thinking abnormal Psychotic disorder	Aggression
Nervous system disorders				
Headaches	Migraine Tremor Dizziness- Dysesthesia Somnolence	Memory impairment Akathisia Balance disorder- Dysgeusia Syncope	Cerebrovascular accident Dyskinesia- Parkinsonism Convulsion	Serotonin syndrome (1)(*) Convulsion (1)(2)
Eye disorders				
		Dry eye-Eye pain Mydriasis Accommodation disorders-Vision blurred visual impairment		
Ear and labyrinth disorders				
		Tinnitus- Vertigo		
Cardiac disorders				
	Tachycardia Palpitations	Arrhythmia- Bundle branch block Extrasystoles Myocardial infarction	Angina pectoris	Takotsubo cardiomyopathy
Vascular disorders				
	Hot flush Hypertension	Raynaud's phenomenon Hypotension- Orthostatic hypotension		
Respiratory, thoracic and mediastinal disorders				
		Cough- Dyspnoea Nasal dryness Pharyngeal disorder		
Gastrointestinal disorders				

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Nausea	Constipation- Diarrhoea Abdominal pain- Dyspepsia Vomiting Dry mouth	Colitis - Gastritis Gastrointestinal motility disorders Abdominal discomfort Abdominal distension Gastroduodenal ulcer Haemorrhoids Stomatitis		
Hepatobiliary disorders				
		Hepatic enzyme increased	Hepatitis - Hepatocellular injury	cytolytic hepatitis (1)
Skin and subcutaneous tissue disorders				
	Pruritus - Rash Hyperhidrosis	Urticaria Dermatitis - Dermatosis	Photosensitivity reaction	Stevens-Johnson syndrome
Musculoskeletal and connective tissue disorders				
	Musculoskeletal pain	Muscle rigidity Myalgia		
Renal and urinary disorders				
	Dysuria - Pollakiuria	Chromaturia - Urinary incontinence Urinary retention		
Reproductive system and breast disorders				
	Ejaculation disorders Erectile dysfunction Testicular pain	Amenorrhea Menorrhagia Menstrual disorder Metrorrhagia Prostatic disorder		Postpartum haemorrhage(**)
General disorders and administration site conditions				
	Fatigue	Pyrexia Chest pain - Chills Feeling abnormal - Malaise		

(1) Estimated frequency of post-marketing surveillance reported adverse reactions; not observed in placebo-controlled clinical trials.

(2) Observed especially in patients with past history of epilepsy

(3) see section 4.4.

(*) A serotonin syndrome, particularly when milnacipran medication is combined with other agents (see section 4.5), characterised by at least three symptoms including changes in psychiatric state and behaviour (excitement, confusion, anxiety, agitation, delirium and restlessness), motor dysfunction (tremor, rigidity, myoclonus, hyperreflexia, and ataxia), hypotension or hypertension and autonomic symptoms such as sweating, fever, shivering and diarrhoea may occur.

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(**) This event has been reported for the therapeutic class of SSRIs/SNRIs (see sections 4.4, 4.6).

Cases of suicidal behaviour and suicidal ideations have been reported during Milnacipran therapy or early after treatment discontinuation (see section 4.4).

Withdrawal syndrome
A few cases of potential withdrawal reactions were reported after Milnacipran treatment discontinuation. Generally, for SSRIs and SNRIs, the symptoms are mild to moderate and self-limiting; however, in some patients they may be severe and/or prolonged. It is therefore advised that when Milnacipran treatment is no longer required, gradual discontinuation by dose tapering should be carried out (see section 4.2 and 4.4).

Additional reactions reported from post-marketing experience in depression indication (frequency not known)
Some other adverse reactions reported during the post-marketing experience in depressed patients were related to the depressive illness:

- elimination of psychomotor inhibition, with suicidal risk
- mood switch with episodes of mania
- reactivation of a delusion in psychotic patients
- paroxysmal manifestations of anxiety (for psychostimulant antidepressants)

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il.

4.9. Overdose

Cases of overdosage have been observed with Milnacipran.
With high doses, the emetic effect can considerably limit the risk of overdosage.
With a 200 mg dose, the following events have commonly been observed (> 10%): nausea, excessive sweating, and constipation.
With doses of 800 mg to 1 g in single-drug therapy, the main symptoms observed are: vomiting, respiratory difficulties (apneic spells), and tachycardia.
After a massive dose (1.9 g to 2.8 g) in combination with other drugs (in particular, benzodiazepines), the following additional symptoms occur: drowsiness, hypercapnia and alterations of consciousness.

Treatment of overdosage:
There is no specific antidote for Milnacipran.
Treatment is symptomatic, with gastric lavage and activated charcoal as soon as possible after oral ingestion.
Medical monitoring should be continued for at least 24 hours.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group**:** Antidepressants, other antidepressants,
ATC code: N06AX17

Milnacipran is a dual inhibitor of (5-HT) serotonin and noradrenaline (NA) re-uptake.
Unlike most tricyclic antidepressants, milnacipran has no affinity for α_1-adrenergic or H_1-histaminergic receptors.

Binding experiments suggest that milnacipran has no significant affinity for cholinergic (muscarinic) receptors.
Furthermore, milnacipran also has no affinity for dopamine D_1 and D_2, benzodiazepine and opioid receptors.

In humans:

- At therapeutic dose, plasma concentrations are constantly located at levels corresponding to a 50 to 90% inhibition of norepinephrine and serotonin re-uptake.
- The pharmacological effects observed in the gastro-intestinal and genito-urinary system appear to be related to inhibition of norepinephrine re-uptake which can exert an antagonistic effect on acetylcholine (indirect anticholinergic effect);
- Milnacipran does not induce any clinically significant change in cardiac repolarization or conduction;
- It does not affect cognitive function and has little sedative effect;
- Sleep disturbances improve in depressed patients treated with milnacipran. The latency time to fall asleep is reduced and also the number of night awakenings and the latency for onset of paradoxal sleep is increased. Total duration of sleep is increased.

The efficacy of milnacipran has been compared to that of tricyclic antidepressants and SSRI and has found to be less than that of clomipramine.

5.2 Pharmacokinetic properties

Absorption
Milnacipran is well absorbed following oral administration. Bioavailability is about 85%. It is not affected by food.
The peak plasma concentration (C_{max}) is reached approximately 2 hours **(**T_{max}) after oral administration. This concentration is about 120 ng/ml after a single 50 mg dose. Concentrations increase proportionally with doses up to 200 mg per administration.
After repeated doses, steady state is reached within 2 to 3 days, with an increase in concentrations of around 70% to 100% compared to a single dose (C_{max} = 216 ng/ml). Inter-individual variability is low.

Distribution
Protein binding is low (13%) and not saturable.
The distribution volume of milnacipran is around 5 l/kg with a total clearance of approximately 40 l/hr.

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Renal and non-renal clearances are equivalent.

Biotransformation
Milnacipran is metabolized mainly by glucuronic acid conjugation.
Active metabolites have been found at very low levels without clinical relevance.

Elimination
Plasma elimination half-life is approximately 8 hours.
Elimination occurs mainly via the kidney (90% of the administered dose) with tubular secretion of the product in unchanged form.
After repeated doses, milnacipran is totally eliminated two to three days after termination of therapy.

High risk patients
Patients with impaired liver function
Hepatic impairment does not significantly affect the pharmacokinetics of milnacipran.

Patients with renal failure
In case of renal failure, milnacipran is eliminated more slowly, in proportion to the degree of renal function alteration (see section 4.2).

Patients aged over 65
Milnacipran's pharmacokinetic parameters are not significantly altered in the elderly. However, physiological alteration of renal function should be taken into account (see section 4.2).

5.3 Preclinical safety data

The main target organs are the liver probably due to an adaptive mechanism and the nervous system.
Milnacipran is neither mutagenic nor carcinogenic.
Milnacipran affected fertility in rats and induced embryolethality with no safety margin.
Experimental data do not reveal any teratogenic potential of Milnacipran.
The administration of Milnacipran in rats during the last third of the gestation and during the lactation induce signs of toxicity in the dams, and effects on the viability, growth and development of the youth. Reproductive parameters from the youth (impaired fertility of females) are affected at dose levels inducing lower body weight gain.

No safety margin to human exposure was established from the pre- and postnatal development studies.

The excretion of Milnacipran and/or metabolites into the milk is observed after the administration of Milnacipran to lactating rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Powder

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Calcium hydrogen phosphate dihydrate
Carmellose calcium
Povidone K30
Colloidal anhydrous silica
Magnesium stearate
Talc

Capsule
Gelatin
Titanium dioxide (E171)
Yellow iron oxide (E172)
Red iron oxide (E172)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date is indicated on the printing materials.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium/PVC-PVDC blister.
Packs containing 14, 28 and 56 hard capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

BioAvenir Ltd., 1 David Hamelech St., Herzelia Pituach

8. MARKETING AUTHORISATION NUMBER(S)

Miln-Avnir 25 mg: 169-70-36192-00
Miln-Avnir 50 mg: 169-71-36193-00

Revised in June 2022 according to MOH guidelines.