Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Clopixol 200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 200 mg zuclopenthixol decanoate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, yellowish oil, practically free from particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The management of schizophrenia and allied psychoses.

4.2 Posology and method of administration

Posology
Adults
The dosage should be adjusted according to the severity of the patient's symptoms. The usual dose range is 200-400 mg every two to four weeks depending on the response of the individual patient.

If volumes larger than 2-3 ml of the 200 mg/ml solution are required, the more concentrated solution (zuclopenthixol decanoate 500 mg/ml) should be preferred.

The maximum recommended dose is 600 mg weekly. Patients who have not previously received depot neuroleptics are usually started on an initial dose of 100 mg.

A few patients may need higher doses or shorter intervals between doses. Injection volumes exceeding 2 ml should be distributed between two injection sites (administration on both injection sites in total should not exceed 600mg).

When changing the medication from oral zuclopenthixol or zuclopenthixol acetate i.m. to maintenance treatment with zuclopenthixol decanoate the following guidelines should be used:

1) Change from oral zuclopenthixol to zuclopenthixol decanoate
x mg p.o. daily corresponds to 8x mg decanoate every two weeks.
x mg p.o. daily corresponds to 16x mg decanoate every four weeks.

Numerical example:
10 mg p.o. daily corresponds to 80 mg decanoate every two weeks.
10 mg p.o. daily corresponds to 160 mg decanoate every four weeks.

Oral zuclopenthixol should be continued during the first week after the first injection but in diminishing dosage.

2) Change from zuclopenthixol acetate to zuclopenthixol decanoate
Concomitantly with the (last) injection of zuclopenthixol acetate (100 mg), 200-400 mg (1-2 ml) of zuclopenthixol decanoate 200 mg/ml should be given intramuscularly and repeated every 2nd week. Higher doses or shorter intervals may be needed.

Zuclopenthixol acetate and zuclopenthixol decanoate can be mixed in a syringe and given as one injection (co-injection).

Patients being transferred from other depot preparations should receive a dose in the ratio of 200 mg zuclopenthixol decanoate equivalent to 25 mg fluphenazine decanoate, to 40 mg cis(Z)-flupentixol decanoate, or to 50 mg haloperidol decanoate.

Subsequent doses of zuclopenthixol decanoate and interval between injections should be adjusted to the response of the patient.

Older people
Older people should receive dosages in the lower end of the dosage range.

Children
Clopixol Injection is not indicated for children

Reduced renal function
Clopixol Depot can be given in usual doses to patients with reduced renal function.

Reduced hepatic function
Dose reduction (relative to the degree of hepatic impairment) should be considered. If possible, where assay facilities exist dosage should be adjusted according to serum levels.

Method of administration
Clopixol Depot is administered by intramuscular injection into the upper outer quadrant of the gluteal region. Injection volumes exceeding 2 ml should be distributed between two injection sites.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Circulatory collapse
- Depressed level of consciousness due to any cause (e.g. intoxication with alcohol, barbiturates or opiates)
- Coma
- Use in children
- Use in senile confusional states

4.4 Special warnings and precautions for use

Tardive dyskinesia can occur with neuroleptic treatment. It is more common at high doses for prolonged periods but has been reported at lower dosage for short periods. The risk seems to be greater in older people, especially females. It has been reported that fine vermicular movements of the tongue are an early sign. It has been observed occasionally in patients receiving zuclopenthixol. The concurrent use of anticholinergic antiparkinson drugs may exacerbate this effect. The potential irreversibility and seriousness, as well as the unpredictability of the syndrome, requires especially careful assessment of the risk versus benefit, and the lowest possible dosage and duration of treatment consistent with therapeutic efficacy. Short-lived dyskinesia may occur after abrupt withdrawal of the drug.

The hormonal effects of antipsychotic neuroleptic drugs include hyperprolactinaemia, which may be associated with galactorrhoea, gynaecomastia, oligomenorrhoea or amenorrhoea. Sexual function, including erection and ejaculation may be impaired; but increased libido has also been reported.

The possibility of development of neuroleptic malignant syndrome exists with any neuroleptic. The risk is possibly greater with the more potent agents. Patients with pre-existing organic brain syndrome, mental retardation and opiate and alcohol abuse are over-represented among fatal cases. Rare cases reported as NMS have also been received in association with zuclopenthixol. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, sweating and cardiac arrhythmia). Additional signs may include elevated creatinine, phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. If a patient develops signs and symptoms indicative of NMS or presents with unexplained high fever without additional clinical manifestations of NMS, all neuroleptic medication, including zuclopenthixol must be discontinued. Symptoms may persist for more than a week after oral neuroleptics are discontinued and somewhat longer when associated with the depot forms of the drugs.

Extrapyramidal reactions may occur, especially during the first few days after an injection and in the early phase of treatment. In most cases these side effects can be satisfactorily controlled by reduction of dosage and/or use of antiparkinsonian drugs. The routine prophylactic use of antiparkinsonian drugs is not recommended. Antiparkinsonian drugs do not alleviate tardive dyskinesia and may aggravate them. Reduction in dosage or, if possible, discontinuation of zuclopenthixol therapy is recommended. In persistent akathisia a benzodiazepine or propranolol may be useful.

Dysphagia can occur secondary to Extrapyramidal symptoms as well to Sialorrhea, Sedation and Neuroleptic malignant syndrome and may lead to life-threatening complications such as aspiration pneumonia and choking.

Like other antipsychotics zuclopenthixol decanoate should be used with caution in patients with organic brain syndrome, convulsion and advanced hepatic disease.

Zuclopenthixol should also be used with cautionin patients who are excitable or overactive, in patients with convulsive disorders, severe atherosclerosis, severe respiratory disease and Parkinson's disease. Care should also be taken in patients with personal or family history of narrow angle glaucoma. Administration to patients with Parkinsonism or extrapyramidal disease may induce an exacerbation of that disorder.

As described for other psychotropics zuclopenthixol decanoate may modify insulin and glucose responses calling for adjustment of the antidiabetic therapy in diabetic patients.

The general caution for use of neuroleptics in hypothyroidism, thyrotoxicosis, myasthenia gravis or prostatic hypertrophy should be observed, but there is no evidence to suggest that zuclopenthixol gives rise to any particular problem in such conditions.

Patients on long-term therapy, particularly on high doses, should be monitored carefully and evaluated periodically to decide whether the maintenance dosage can be lowered.

As with other drugs belonging to the therapeutic class of antipsychotics, zuclopenthixol decanoate may cause QT prolongation. Persistently prolonged QT intervals may increase the risk of malignant arrhythmias. Therefore, zuclopenthixol decanoate should be used with caution in susceptible individuals (with hypokalaemia, hypomagnesaemia or family history of QT prolongation) and in patients with a history of cardiovascular disorders, e.g. QT prolongation, significant bradycardia (<50 beats per minute), a recent acute myocardial infarction, uncompensated heart failure, or cardiac arrhythmia. Concomitant treatment with other antipsychotics should be avoided (see section 4.5).

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Clopixol and preventive measures undertaken.

Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics, including zuclopenthixol decanoate. Long-acting depot antipsychotics should be used with caution in combination with other medicines known to have a myelosuppressive potential, as these cannot rapidly be removed from the body in conditions where this may be required.

Older people
Care should also be taken in older people, particularly if frail or at risk of hypothermia, sedation, hypotension or confusion.

Cerebrovascular
An approximately 3-fold increased risk of cerebrovascular adverse events have been seen in randomised placebo controlled clinical trials in the dementia population with some atypical antipsychotics. The mechanism for this increased risk is not known. An increased risk cannot be excluded for other antipsychotics or other patient populations. Zuclopenthixol decanoate should be used with caution in patients with risk factors for stroke.

Increased Mortality in Older People with Dementia
Data from two large observational studies showed that older people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known.

Zuclopenthixol is not licensed for the treatment of dementia-related behavioural disturbances.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations requiring precautions for use

Zuclopenthixol may enhance the sedative effect of alcohol, and the effects of barbiturates and other CNS depressants and may potentiate the effects of general anaesthetics.

Zuclopenthixol may reduce the effect of levodopa and the effect of adrenergic drugs.

Concomitant use of metoclopramide and piperazine increases the risk of extrapyramidal disorder.

Neuroleptics may increase or reduce the effect of antihypertensive drugs, the antihypertensive effect of guanethidine and similar acting compounds is reduced.

Concomitant use of neuroleptics and lithium increases the risk of neurotoxicity.

Tricyclic antidepressants and neuroleptics mutually inhibit the metabolism of each other.

Neuroleptics may enhance the absorption of corticosteroids and digoxin, the hypotensive effects of vasodilator antihypertensive agents such as hydralazine and prolong the action of neuromuscular blocking agents.

Since zuclopenthixol is partly metabolised by CYP2D6, concomitant use of drugs known to inhibit this enzyme may lead to decreased clearance of zuclopenthixol.

As for other atypical antipsychotics, caution is advised in patients taking zuclopenthixol in concomitant use with oral anticoagulants (e.g. warfarin), and other medicinal products known to affect platelet function (e.g. phenothiazines, most tricyclic antidepressants, acetylsalicyclic acid, and non-steroidal anti-inflammatory medicinal products (NSAIDs), ticlopidine and dipyridamole).

Increases in the QT interval related to antipsychotic treatment may be exacerbated by the co-administration of other drugs known to significantly increase the QT interval. Co-administration of such drugs should be avoided. Relevant classes include:

- class Ia and III antiarrhythmics (e.g. quinidine, amiodarone, sotalol, dofetilide)
- some antipsychotics (e.g. thioridazine)
- some macrolides (e.g. erythromycin)
- some antihistamines (e.g. terfenadine, astemizole)
- some quinolone antibiotics (e.g. gatifloxacin, moxifloxacin)

The above list is not exhaustive and other individual drugs known to significantly increase QT interval (e.g. cisapride, lithium) should be avoided.

Drugs known to cause electrolyte disturbances such as thiazide diuretics (hypokalaemia) and drugs known to increase the plasma concentration of zuclopenthixol decanoate should also be used with caution as they may increase the risk of QT prolongation and malignant arrhythmias (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Zuclopenthixol decanoate should not be administered during pregnancy unless the expected benefit to the patient outweighs the theoretical risk to the foetus.

Neonates exposed to antipsychotics (including zuclopenthixol) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Consequently, newborns should be monitored carefully.

Animal studies have shown reproductive toxicity (see section 5.3).

Breast-feeding
As zuclopenthixol is found in breast milk in low concentrations, breast-feeding should not be continued during therapy unless in the opinion of the physician the expected benefit to the patient outweighs the potential risk to the infant.

Fertility
In humans, adverse events such as hyperprolactinaemia, galactorrhoea, amenorrhoea, erectile dysfunction and ejaculation failure have been reported (see section 4.8). These events may have a negative impact on female and/or male sexual function and fertility.

If clinically significant hyperprolactinaemia, galactorrhoea, amenorrhoea or sexual dysfunctions occur, a dose reduction (if possible) or discontinuation should be considered. The effects are reversible on discontinuation.

Animal studies have shown impaired mating and reduced conception rate (see section 5.3).

4.7 Effects on ability to drive and use machines

Clopixol Depot is a sedative drug. Patients who are prescribed psychotropic medication may be expected to have some impairment in general attention and concentration and should be cautioned about their ability to drive or operate machinery.

4.8 Undesirable effects

Undesirable effects are for the majority dose dependent. The frequency and severity are most pronounced in the early phase of treatment and decline during continued treatment.

Frequencies are taken from the literature and spontaneous reporting. Frequencies are defined as:
very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10000 to <1/1000), very rare (<1/10000), or not known (cannot be estimated from the available data).

Blood and lymphatic system disorders	Rare	Thrombocytopenia, neutropenia, leukopenia, agranulocytosis.
Immune system disorders	Rare	Hypersensitivity, anaphylactic reaction.
Endocrine disorders	Rare	Hyperprolactinaemia.
Metabolism and nutrition disorders	Common	Increased appetite, weight increased.
	Uncommon	Decreased appetite, weight decreased.
	Rare	Hyperglycaemia, glucose tolerance impaired, hyperlipidaemia.
Psychiatric disorders	Common	Insomnia, depression, anxiety, nervousness, abnormal dreams, agitation, libido decreased.
	Uncommon	Apathy, nightmare, libido increased, confusional state.
Nervous system disorders	Very common	Somnolence, akathisia, hyperkinesia, hypokinesia, extrapyramidal symptoms (see section 4.4).
	Common	Tremor, dystonia, hypertonia, dizziness, headache, paraesthesia, disturbance in attention, amnesia, gait abnormal.
	Uncommon	Tardive dyskinesia, hyperreflexia, dyskinesia, parkinsonism, syncope, ataxia, speech disorder, hypotonia, convulsion, migraine.
	Very rare	Neuroleptic malignant syndrome.
Eye disorders	Common	Accommodation disorder, vision abnormal.

	Uncommon	Oculogyration, mydriasis.
Ear and labyrinth disorders	Common	Vertigo.
	Uncommon	Hyperacusis, tinnitus.
Cardiac disorders	Common	Tachycardia, palpitations.
	Rare	Electrocardiogram QT prolonged.
Vascular disorders	Uncommon	Hypotension, hot flush.
	Very rare	Venous thromboembolism
Respiratory, thoracic and mediastianal disorders	Common	Nasal congestion, dyspnoea.
Gastrointestinal disorders	Very common	Dry mouth.
	Common	Salivary hypersecretion, constipation, vomiting, dyspepsia, diarrhoea.
	Uncommon	Abdominal pain, nausea, flatulence.
	Rare	Dysphagia* (see section 4.4)
Hepato-biliary disorders	Uncommon	Liver function test abnormal.
	Very rare	Cholestatic hepatitis, jaundice.
Skin and subcutaneous tissue disorders	Common	Hyperhidrosis, pruritus.
	Uncommon	Rash, photosensitivity reaction, pigmentation disorder, seborrhoea, dermatitis, purpura.
Musculoskeletal and connective tissue disorder	Common	Myalgia.
	Uncommon	Muscle rigidity, trismus, torticollis.
Renal and urinary disorders	Common	Micturition disorder, urinary retention, polyuria.
Pregnancy, puerperium and perinatal conditions.	Not known	Drug withdrawal syndrome neonatal (see 4.6)
Reproductive system and breast disorders	Uncommon	Ejaculation failure, erectile dysfunction, female orgasmic disorder, vulvovaginal dryness.
	Rare	Gynaecomastia, galactorrhoea, amenorrhoea, priapism.
General disorders and administration site conditions	Common	Asthenia, fatigue, malaise, pain.
	Uncommon	Thirst, injection site reaction, hypothermia, pyrexia.

**Dysphagia can occur secondary to extrapyramidal symptoms as well to sialorrhea, sedation, and neuroleptic malignant syndrome and may lead to life-threatening complications such as aspiration pneumonia and choking*.

Localised erythema, pruritus and injection site nodule are the most typical injection site reactions.
As with other drugs belonging to the therapeutic class of antipsychotics, rare cases of QT prolongation, ventricular arrhythmias - ventricular fibrillation, ventricular tachycardia, Torsade de Pointes and sudden unexplained death have been reported for zuclopenthixol decanoate (see section 4.4).

Abrupt discontinuation of zuclopenthixol decanoate may be accompanied by withdrawal symptoms. The most common symptoms are nausea, vomiting, anorexia, diarrhoea, rhinorrhoea, sweating, myalgias, paraesthesias, insomnia, restlessness, anxiety, and agitation. Patients may also experience vertigo, alternate feelings of warmth and coldness, and tremor. Symptoms generally begin within 1 to 4 days of withdrawal and abate within 7 to 14 days.

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

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

Due to the administration form overdose symptoms are unlikely to occur.

Symptoms

Somnolence, coma, movement disorders, convulsions, shock, hyperthermia/hypothermia.

ECG changes, QT prolongation, Torsade de Pointes, cardiac arrest and ventricular arrhythmias have been reported when administered in overdose together with drugs known to affect the heart.

Treatment

Treatment is symptomatic and supportive. Measures to support the respiratory and cardiovascular systems should be instituted. Epinephrine (adrenaline) should not be used as further lowering of blood pressure may result. Convulsions may be treated with diazepam and movement disorders with biperiden.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group
Neuroleptics (antipsychotics)
ATC-code: N 05 AF 05

Mechanism of action
Zuclopenthixol is a neuroleptic of the thioxanthene group.

The antipsychotic effect of neuroleptics is related to their dopamine receptor blocking effect but possibly also 5-HT (5-hydroxytryptamine) receptor blockade contributes.
In vitro zuclopenthixol has high affinity for both dopamine D_1 and D_2 receptors, for a_1-adrenoceptors and 5-HT_2 receptors but no affinity for cholinergic muscarine receptors. It has weak histamine (H_1) receptor affinity and no a_2-adrenoceptor blocking activity.

In vivo the affinity for D_2 binding sites dominates over the affinity for D_1 receptors. Zuclopenthixol has proven to be a potent neuroleptic in all the behavioural studies for neuroleptic (dopamine receptor blocking) activity. Correlation is found in the *in vivo* test models, the affinity for dopamine D_2 binding sites *in vitro* and the average, daily oral antipsychotic doses.

Like most other neuroleptics zuclopenthixol increases the serum prolactin level.

Pharmacological studies have clearly demonstrated that zuclopenthixol decanoate in oil has a prolonged neuroleptic effect and that the amount of drug necessary to maintain a certain effect over a long period is considerably smaller with the depot preparation than with daily oral administration of zuclopenthixol. In terms of clinical use the findings in pharmacological studies may indicate that a prolonged neuroleptic effect without overt sedation may be obtained with the depot preparation. Moreover, the risk of interference with anaesthetics may be expected to be low.

Clinical efficacy and safety
In clinical use zuclopenthixol decanoate is intended for the maintenance treatment of chronic psychotic patients. Positive results also have been obtained in the management of hyperactive and aggressive mentally handicapped patients.

Zuclopenthixol decanoate induces a transient dose-dependent sedation. However, if the patient is switched to maintenance treatment with zuclopenthixol decanoate from oral zuclopenthixol or from i.m. zuclopenthixol acetate the sedation will be no problem. Tolerance to the unspecific sedative effect develops rapidly.

Zuclopenthixol decanoate is particularly useful in the treatment of patients, who are agitated, restless, hostile, or aggressive.

Zuclopenthixol decanoate permits continuous treatment especially of those patients who are unreliable in taking the oral medication prescribed for them. Zuclopenthixol decanoate thus prevents the frequent relapses due to noncompliance in patients on oral medication.

5.2 Pharmacokinetic properties

Absorption
By esterification of zuclopenthixol with decanoic acid zuclopenthixol has been converted to a highly lipophilic substance, zuclopenthixol decanoate. When dissolved in oil and injected intramuscularly the ester diffuses rather slowly from the oil to the body water phase where it is rapidly hydrolysed releasing the active zuclopenthixol.

Following intramuscular injection maximum serum concentration is reached over a period of 3-7 days. With an estimated half-life of 3 weeks (reflecting the release from the depot) steady state conditions will be attained after about 3 months' repeated administration.

Distribution
The apparent volume of distribution $(V_d)_b$ is about 20 l/kg. The plasma protein binding is about 98-99 %.

Biotransformation
The metabolism of zuclopenthixol proceeds along three main routes - sulphoxidation, side chain N-dealkylation and glucuronic acid conjugation. The metabolites are devoid of psychopharmacological activity. Zuclopenthixol dominates over metabolites in brain and other tissues.

Elimination
The elimination half-life ($T_{½\ \beta}$) of zuclopenthixol is about 20 hours and the mean systemic clearance (Cl_s) is about 0.86 l/min.

Zuclopenthixol is excreted mainly with faeces, but also to some degree (about 10 %) with the urine. Only about 0.1 % of the dose is excreted unchanged with the urine, meaning that the drug load on the kidneys is negligible.

In nursing mothers zuclopenthixol is excreted in small amounts with the breast milk. In steady state the pre-dose mean ratio milk conc./serum conc. in women treated orally or with the decanoate was about 0.29.

Linearity
The kinetics is linear. The mean steady state pre-injection serum level of zuclopenthixol corresponding to a 200 mg dose of zuclopenthixol decanoate every two weeks is about 10 ng/ml (25 nmol/l).

Older people
The pharmacokinetic parameters are independent of the age of the patients.

Reduced renal function
Based on the above characteristics for elimination it is reasonable to assume that reduced kidney function is likely not to have much influence on the serum levels of parent drug.

Reduced hepatic function
No data available.

Polymorphism
An *in vivo* investigation has shown that some part of the metabolic pathways is subject to genetic polymorphism of the sparteine/debrisoquine oxidation (CYP2D6).

Pharmacokinetic / Pharmacodynamic relationship
A pre-injection serum (plasma) concentration of 2.8-12 ng/ml (7-30 nmol/l) and a max./min. fluctuation < 2.5 is suggested as a guideline for maintenance treatment of schizophrenic patients with a low-moderate degree of illness. Pharmacokinetically a dose of 200 mg/2 weeks or 400 mg/4 weeks of zuclopenthixol decanoate is equivalent to a daily oral dose of 25 mg zuclopenthixol.

5.3 Preclinical safety data

Acute toxicity
Zuclopenthixol has low acute toxicity.

Chronic toxicity
In chronic toxicity studies there were no findings of concern for the therapeutic use of zuclopenthixol.

Reproductive toxicity
In a three-generation study in rats a delay in mating was noted. Once mated there was no effect on fertility. In an experiment where zuclopenthixol was administered via the diet, impaired mating performance and reduced conception rate was noted.

Animal reproduction studies have not shown evidence of embryotoxic or teratogenic effects.
In a peri/postnatal study in rats, dosages of 5 and 15 mg/kg/day resulted in an increase of stillbirths, reduced pup survival and delayed development of pups.

The clinical significance of these findings is unclear and it is possible that the effect on pups was due to neglect from the dams that were exposed to doses of zuclopenthixol producing maternal toxicity.

Mutagenicity and carcinogenicity
Zuclopenthixol has no mutagenic or carcinogenic potential. In a rat oncogenecity study 30 mg/kg/day for two years (top dosage) resulted in slight non-statistical increases in the incidence of mammary adenocarcinomas, pancreatic islet cell adenomas, carcinomas in females and thyroid parafollicular carcinomas. The slight increase in the incidence of these tumors is a common finding for D_2 antagonists, which increase prolactin secretion when administered to rats. The physiological differences between rats and humans with regard to prolactin make the clinical significance of these findings unclear, but it is accepted as not predicting an oncogenic risk in patients.

Local toxicity
Local muscle damage is seen after injection of aqueous solutions of neuroleptics, including zuclopenthixol. The muscle damage shows a much higher degree after the aqueous solution of neuroleptics than after the oily solutions of zuclopenthixol acetate and zuclopenthixol decanoate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium chain

6.2 Incompatibilities

In the absence of compatability studies, this medicinal product must not be mixed with the medicinal products apart from other injections in the Clopixol range.

6.3 Shelf life

Unopened: 3 years.

Once opened, use immediately and discard any unused solution.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

Colourless ampoules (Type 1 glass) of 1 ml.
Pack size: 10 ampoules per box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

7 MARKETING AUTHORISATION HOLDER

Lundbeck (Ireland) Limited
4045 Kingwood Road
Citywest Business Park
Citywest
Dublin
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8 MARKETING AUTHORISATION NUMBER

PA0776/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 June 1977

Date of last renewal: 01 November 2007

10 DATE OF REVISION OF THE TEXT

January 2026