AUSTRALIAN PRODUCT INFORMATION

Fluanxol® Depot
Fluanxol® Concentrated Depot

SOLUTION FOR INJECTION

1 NAME OF THE MEDICINE

Flupentixol decanoate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluanxol Depot
- Solution for injection containing 20 mg/mL flupentixol decanoate.

Fluanxol Concentrated Depot
- Concentrated injection containing 100 mg/mL flupentixol decanoate.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Flupentixol decanoate is insoluble in water, soluble in alcohol, ether and chloroform.

Fluanxol Depot injection presents as a clear, colourless to slightly yellowish oil.

Fluanxol Concentrated Depot injection presents as a clear, yellowish to yellow oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Flupentixol is indicated for the maintenance treatment of chronic schizophrenia and other related chronic psychoses, in patients intolerant of and/or refractory to other depot preparations.

Flupentixol is intended for maintenance therapy and not for short-term use (less than 3 months).

4.2 Dose and method of administration

Adults

Fluanxol (flupentixol decanoate) is administered by intramuscular injection, in the gluteus maximus. Fluanxol is NOT for intravenous use. It is not intended for short-term therapy (less than 3 months).

As a long-acting depot preparation, Fluanxol has been found useful in the maintenance treatment of non-agitated chronic schizophrenic patients who have been stabilised with short-acting neuroleptics and might benefit from transfer to a longer-acting injectable medication. The changeover of medication should aim at maintaining a clinical outcome similar to or better than that obtained with the previous therapy. To achieve and maintain the optimum dose, the changeover from other neuroleptic medication should proceed gradually and constant supervision is required during the period of dosage adjustment in order to minimise the risk of overdosage or insufficient suppression of psychotic symptoms before the next injection.

Patients not previously treated with long-acting depot neuroleptics should be given an initial test dose of 5 mg to 20 mg. An initial dose of 20 mg is usually well tolerated: however, a 5 mg test dose is recommended in elderly, frail and cachectic patients, and in patients whose individual or family history suggests a predisposition to extrapyramidal reactions. In the subsequent 5 to 10 days, the therapeutic response and the appearance of extrapyramidal symptoms should be carefully monitored. Oral neuroleptic drugs may be continued, but in diminishing dosage, during this period.

In patients previously treated with long-acting depot neuroleptics who displayed good tolerance to these drugs, an initial dose of 20 to 40 mg may be adequate. Patients transferred from fluphenazine decanoate should receive flupentixol decanoate in a dose ratio of 25 mg fluphenazine decanoate equals 40 mg flupentixol decanoate. For haloperidol decanoate, dose equivalence has not been systematically established, but is approximately 40 mg flupentixol decanoate equals 50 mg haloperidol decanoate.

Subsequent doses and the frequency of administration must be determined for each patient. There is no reliable dosage comparability between a shorter-acting neuroleptic and depot flupentixol, and therefore, the dosage of the long-acting drug must be individualised.

Except in particularly sensitive patients, a second dose of 20 mg or 40 mg can be given 4 to 10 days after the initial injection. Subsequent dosage adjustments are made in accordance with the response of the patient, but the majority of patients can be

Stroke - An approximate 3-fold increase in risk of cerebrovascular adverse events has 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. Therefore, flupentixol decanoate should be used with caution in patients with risk factors for stroke.

Convulsions - Flupentixol should be used with caution in patients with a history of convulsions since it may lower the convulsive threshold.

Anticholinergic effects - Although its anticholinergic properties are weak, flupentixol should be used with caution in patients who are known or are suspected to have glaucoma, and in those patients who might be exposed to extreme heat, or organophosphorus insecticides or who are receiving atropine or related drugs. Paralytic ileus has occasionally been reported, particularly in the elderly, when several drugs with anticholinergic effects have been used simultaneously.

White blood cell disorders - Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics, including flupentixol.

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.

Laboratory tests required - Blood dyscrasias and liver damage have been reported sporadically with this class of drugs including Fluanxol. Therefore, routine blood counts and hepatic function tests are advisable, particularly during the first months of therapy. Should either of these disorders occur, supportive treatment should be instituted and further injections avoided.

Cellular depression - If any soreness of the mouth, gums or throat or any symptoms of upper respiratory infection occur and confirmation leukocyte count indicates cellular depression, therapy should be discontinued and other appropriate measures instituted immediately.

Cardiac disorders - Caution should be observed when using a drug of this category in patients who may have a propensity for development of defects in cardiac conduction.

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

Venous thromboembolism (VTE) – cases 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 flupentixol decanoate and preventive measures undertaken.

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

Surgery - Patients on large doses of flupentixol who are undergoing surgery should be watched carefully for possible hypotensive phenomena, and dosages of anaesthetic or central nervous system depressant agents may have to be reduced.

Monitoring - Patients on long-term therapy, particularly on high doses, should be evaluated periodically to decide whether the maintenance dosage can be lowered or drug therapy discontinued.

Persistent tardive dyskinesia - Tardive dyskinesia may develop in some patients on long-term therapy with antipsychotic medications or may occur after therapy has been discontinued. The risk seems to be greater in elderly patients on high dose therapy, especially females. The symptoms are potentially irreversible in some patients. The syndrome is characterised by rhythmical involuntary movements of the tongue, face, mouth or jaw. Sometimes these may be accompanied by involuntary movements of the extremities. There is no known effective treatment available for tardive dyskinesia; antiparkinson agents usually do not alleviate the symptoms. It is suggested that all antipsychotic agents be gradually reduced and withdrawn, if possible, if these symptoms appear. It has been reported that fine vermicular movements of the tongue may be the first sign of the syndrome and if medication is stopped at this time the syndrome may remit. If it is necessary to reinstitute treatment or increase the dosage or change to a different antipsychotic agent, the syndrome may be masked.

adequately controlled by 20 to 40 mg of Fluanxol every 2 to 4 weeks. The optimal amount of the drug has been found to vary with the clinical circumstances and individual response.

Since higher doses increase the incidence of extrapyramidal reactions and other adverse effects, the amount of drug used should not be increased merely in order to prolong the intervals between injections. With higher doses there may also be more variability in the action of Fluanxol and, therefore, unit dose increments should not exceed 20 mg (1.0 mL). If volumes larger than 2 - 3 mL of the 20 mg/mL solution are required, the 100 mg/mL should be preferred. After an appropriate dosage adjustment is achieved, regular and continuous supervision and reassessment is considered essential in order to permit any further dosage adjustments that might be required to ensure use of the lowest effective individual dose and avoid troublesome side effects.

Fluanxol Concentrated Depot
Doses greater than 100 mg/fortnight are usually not deemed necessary although higher doses have been used occasionally in some treatment-resistant patients.
Patients who require higher doses of Fluanxol Depot to control symptoms of schizophrenia and/or those who complain of discomfort with a large injection volume may be administered Fluanxol Concentrated Depot (100 mg/mL) in preference to Fluanxol Depot (20 mg/mL).

AS WITH ALL OILY INJECTIONS IT IS IMPORTANT TO ENSURE, BY ASPIRATION BEFORE INJECTION, THAT INADVERTENT INTRAVASCULAR INJECTION DOES NOT OCCUR.

4.3 Contraindications
Flupentixol is contraindicated in patients with known hypersensitivity to the thioxanthenes. The possibility of cross-sensitivity between the thioxanthenes and phenothiazine derivatives should be considered.

Flupentixol is also contraindicated in patients with known hypersensitivity to the excipient used (fractionated coconut oil) in the injection.

Flupentixol is also contraindicated in the presence of depressed level of consciousness due to any cause (e.g. intoxication with alcohol, barbiturates or opiates), circulatory collapse, coma, and suspected or established subcortical brain damage, blood dyscrasias and phaeochromocytoma.

Flupentixol is not recommended for use in children (see Section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use
Neuroleptic Malignant Syndrome - The neuroleptic malignant syndrome (NMS) is a rare but potentially fatal complication of the use of neuroleptic drugs. Core features of NMS are hyperthermia, muscle rigidity and fluctuating consciousness along with autonomic dysfunction (labile blood pressure, tachycardia, diaphoresis). Aside from immediate cessation of the neuroleptic medication the use of general supportive measures and symptomatic treatment are vital. 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. Note that neuroleptic malignant syndrome has been reported with Fluanxol.

Initiation of therapy - Severe adverse reactions requiring immediate medical attention may occur and are difficult to predict. Therefore, the evaluation of tolerance and response, and establishment of adequate maintenance therapy require careful stabilisation of each patient under continuous, close medical observation and supervision.

Suicide – The possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder, and close supervision of high risk patients should accompany therapy.

Special patient groups - Fluanxol should be used with caution in liver damage, cerebrovascular or renal insufficiency, and severe cardiovascular disorders. It is not indicated for the management of severely agitated psychotic patients, psychoneurotic patients or geriatric patients with confusion and/or agitation, as these characteristics may be exaggerated.

Use in hepatic impairment - Significant reduction of liver function may cause a decrease in the elimination rate of Fluanxol. Careful dosing and, if possible, a serum level determination is advisable in patients with reduced liver function (see also Section 5.2 Pharmacokinetic properties).

Parkinsonism - The drug should be used with caution in patients with Parkinsonism.

Arteriosclerosis - The drug should be used with caution in patients with severe arteriosclerosis.

Organic brain syndrome - Like other neuroleptics, Fluanxol should be used with caution in patients with organic brain syndrome.

Antiemetic effect - The antiemetic effect observed with flupentixol in animal studies may also occur in man; therefore, the drug may mask signs of toxicity due to overdosage of other drugs, or it may mask the symptoms of disease, such as brain tumor or intestinal obstruction.

Paediatric use
Since the safety and efficacy of flupentixol in children have not been established, its use is not recommended in the paediatric age group (see Section 4.3 Contraindications).

Use in the elderly
Increased Mortality in Elderly people with Dementia
Data from two large observational studies showed that elderly 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.

Flupentixol is not approved for the treatment of dementia-related behavioural disturbances.

Effects on laboratory tests
Transient slight alterations in liver function tests have infrequently been reported.

4.5 Interactions with other medicines and other forms of interactions
Tricyclic antidepressants - Tricyclic antidepressants and neuroleptics mutually inhibit the metabolism of each other.

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

MAO Inhibitors - Although no specific clinical incompatibilities have been encountered, on theoretical pharmacodynamic grounds, it may be wise to allow an interval of not less than 2 weeks between completion of MAOI treatment and the initiation of flupentixol treatment.

Alcohol, other CNS depressant drugs - Fluanxol may enhance the sedative effects of alcohol and the effects of barbiturates and other CNS depressants (including opioid analgesics).
As with other neuroleptics, the plasma concentration of flupentixol may be decreased by concomitant administration of phenobarbitone and carbamazepine and influenced by the intake of alcohol.

Hypnotics - As with all phenothiazines, Fluanxol should not be used concomitantly with large doses of hypnotics due to the possibility of potentiation.

Antihypertensives - Neuroleptics may increase or reduce the effect of antihypertensive drugs.

Fluanxol should not be given concomitantly with guanethidine, debrisoquine, clonidine or similarly acting compounds since neuroleptics may block the antihypertensive effect of these compounds.

Levodopa, adrenergic drugs - Fluanxol may lower the effect of levodopa and adrenergic drugs.

Metoclopramide, piperazine - Concomitant use of metoclopramide or piperazine increases the risk of extrapyramidal disorder.

Drugs known to increase the QT interval - 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 the 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 flupentixol decanoate should also be used with caution as they may increase the risk of QT prolongation and malignant arrhythmias (see Section 4.4 Special warnings and precautions for use).

4.6 Fertility, pregnancy and lactation
Effects on fertility
In humans, adverse events such as hyperprolactinaemia, galactorrhoea, amenorrhoea, libido decreased, female orgasmic disorder, vulvovaginal dryness, erectile dysfunction and

ejaculation failure have been reported (see Section 4.8 Adverse effects (undesirable effects)). These events may have a negative impact on female and/or male sexual function and fertility.

If clinical significant hyperprolactinaemia, galactorrhoea, amenorrhoea or sexual dysfunctions occur, a dose reduction (if possible) or discontinuation should be considered.

In preclinical fertility studies in rats, flupentixol slightly affected the pregnancy rate of female rats.

Use in pregnancy-
Category C
Safety in pregnancy has not been established. Therefore, it should not be administered to women of childbearing potential unless, in the opinion of the physician, the expected benefit to the patient outweighs the potential risk to the foetus.

Animal studies have shown reproductive toxicity.

In fertility studies in rats, flupentixol slightly affected the pregnancy rate of female rats.

Animal reproduction studies in mice, rats and rabbits have not shown evidence of teratogenic effects. Foetal effects in terms of increased post implantation loss/increased absorption rates or occasional abortions were seen in rats and rabbits.

Non-teratogenic class effect:
Neonates exposed to antipsychotic drugs (including flupentixol) during the third trimester of pregnancy are at risk of experiencing extrapyramidal neurological disturbances and/or withdrawal symptoms following delivery. There have been post-market reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited; in other cases neonates have required additional medical treatment or monitoring.

Flupentixol should be used during pregnancy only if the anticipated benefit outweighs the risk and administered dose and duration of treatments should be as low and short as possible.

Use in lactation
Small amounts of the drug are excreted in breast milk so that lactating mothers should undertake alternative feeding of the infant.

4.7 Effects on ability to drive and use machines
Although flupentixol is a relatively non-sedating drug, sedation may occur in some patients. Therefore, ambulatory patients should be warned about engaging in activities such as driving a car or operating machinery.

4.8 Adverse effects (Undesirable effects)
The most common adverse reaction reported with flupentixol has been extrapyramidal disorder.

Flupentixol shares many of the pharmacological properties of other thioxanthenes and phenothiazines. Therefore, the known adverse reactions of these drugs should be borne in mind when flupentixol is used.

Autonomic Nervous System
Dry mouth, blurred vision, constipation, excessive salivation, excessive perspiration, nausea, disturbances in micturition, dizziness, palpitations and fainting have been observed with flupentixol but are uncommon. Miosis, mydriasis, paralytic ileus, polyuria, nasal congestion, glaucoma, tachycardia, hypotension, hypertension, fluctuations in blood pressure, non-specific ECG changes and cardiac arrhythmias have been reported with related drugs. If hypotension occurs, adrenaline should not be used as a pressor agent since a paradoxical further lowering of blood pressure may result.

Cardiac Disorders
Cardiac failure, tachycardia and palpitations have been reported. 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 flupentixol decanoate (see Section 4.4 Special warnings and precautions for use).

Central Nervous System
Extrapyramidal symptoms, including hypo- and hyperkinetic states, tremors, pseudoparkinsonism, dystonia, hypertonia, akathisia, oculogyric crises and tardive dyskinesia (see Section 4.4 Special warnings and precautions for use). The symptoms, if they are to occur, usually appear within the first few days after administration and can usually be controlled or totally curtailed by reduction in dosage and/or standard antiparkinsonian medication. The incidence of extrapyramidal symptoms appears to be more frequent with the first few injections of flupentixol and diminish thereafter. The routine prophylactic use of antiparkinsonian medication is not recommended. Extrapyramidal reactions may be alarming, and patients should be forewarned and reassured. Reduction in dosage or, if possible, 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.

Miscellaneous
Sudden, unexpected and unexplained deaths have occasionally been reported in patients who have received certain phenothiazine derivatives. Previous brain damage or seizures may be predisposing factors; high doses should be avoided in known seizure patients. Several patients have shown flare-ups of psychotic behaviour patterns shortly before death. Autopsy findings have usually revealed acute fulminating pneumonia or pneumonitis, aspiration of gastric contents or intramyocardial lesions.

Polymyositis and facial oedema have also been reported.

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 Overdose
In general, the main therapy for all overdoses is supportive and symptomatic care.

Symptoms
Overdosage may cause somnolence, coma, extreme agitation, excitement, confusion, convulsions, extrapyramidal symptoms, shock, respiratory and circulatory collapse and 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. No further injections of flupentixol should be given. Measures to support the respiratory and cardiovascular systems should be instituted. If severe hypotension occurs, an i.v. vasopressor drug should be administered immediately. Epinephrine (adrenaline) should not be used as further lowering of blood pressure may result. Convulsions may be treated with diazepam and extrapyramidal symptoms with an antiparkinsonian medication.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia) and 0800 764 766 (New Zealand).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Mechanism of action
Flupentixol is a potent, relatively non-sedating, neuroleptic drug of the thioxanthene class. In low to moderate dosages (up to 100 mg/2 weeks) Fluanxol is non-sedating, while a sedative effect may be expected when higher doses are administered. Flupentixol shows antipsychotic effects in patients with schizophrenia. It may be of benefit in patients with flat or depressed affect. In low doses, Fluanxol possesses disinhibiting and mood elevating properties.

Flupentixol dose-dependently increases the serum prolactin levels.

Clinical trials
No data available.

5.2 Pharmacokinetic properties
The decanoic acid esterification of flupentixol results in the slow release of the drug from the oily solution at the injection site with consequent prolongation of duration of action. The onset of action usually occurs in the range of 24 to 72 hours after injection and the improvement of symptoms continues for 2 to 4 weeks. A pre-injection serum concentration of 2 - 8 nmol/L is recommended for maintenance treatment of schizophrenic patients with a low - moderate degree of illness. However, there is considerable variation in the individual response of patients to flupentixol decanoate and its use for maintenance therapy requires careful supervision. The maximal serum concentration is reached at the end of the first week after injection. Estimates of half-life varied considerably between studies; elimination is prolonged, in the order of 3 weeks to 3 months and probably reflects release of the active compound from the depot.

Steady state is probably achieved within 3 to 6 months. The depot is administered every 2 to 4 weeks. Limited data suggest that excretion and metabolism proceed along the same routes as found in animals. In one human study urine contained flupentixol, N-dealkyl flupentixol and their corresponding sulphoxides. After an oral dose another study demonstrated a relatively small amount of flupentixol in urine and faeces.

5.3 Preclinical safety data

discontinuation of flupentixol therapy is recommended.

Other CNS effects reported with flupentixol include restlessness, insomnia, overactivity, psychomotor agitation, nervousness, confusional state, speech disorder, involuntary muscle contractions, tics, hyperkinesia, hypokinesia, dyskinesia, hypomania, epiliptiform convulsions, headache, drowsiness, somnolence, depression, fatigue, and anergia.

Neuroleptic malignant syndrome has been reported with Fluanxol (see Section 4.4 Special warnings and precautions for use).

Endocrine Disorders, Metabolism and Nutrition Disorders
Weight changes, increased and decreased appetite, hyperglycaemia, abnormal glucose tolerance, gynaecomastia, impotence, loss of libido, and sexual excitement have been reported with flupentixol. Elevated serum prolactin levels may cause hormonal effects in some patients e.g. menstrual disturbance, galactorrhoea in men and women. Related drugs have been also associated with false positive pregnancy tests, peripheral oedema, gynaecomastia, hypo- and hyperglycaemia and glycosuria. Elevated creatine phosphokinase levels have also been reported.

Eye Disorders
Accommodation disorder and abnormal vision have been reported commonly and oculogyration reported uncommonly with Fluanxol use. Lenticular and corneal opacities have been seen following long-term use of phenothiazines, but not reported with flupentixol.

Gastrointestinal Disorders
Dysphagia, gingival hypertrophy, dry mouth, salivary hypersecretion, constipation, vomiting, dyspepsia, diarrhoea, abdominal pain, nausea, flatulence, hepatitis and hepatic failure have been reported.

General Disorders and Administration Site Conditions
Asthenia and fatigue have been commonly reported. Local inflammation and abscess at injection site have also been reported.

Hepatobiliary Disorders
Abnormal liver function test has been reported uncommonly and jaundice very rarely.

Musculoskeletal and Connective Tissue Disorders
Myalgia has been reported commonly and muscle rigidity uncommonly reported.

Pregnancy, puerperium and perinatal conditions
Neonatal drug withdrawal syndrome – frequency not known.

Renal and Urinary Disorders
Micturition disorder and urinary retention have been commonly reported.

Reproductive System and Breast Disorders
Ejaculation failure and erectile dysfunction have been reported uncommonly and gynaecomastia, galactorrhoea and amenorrhoea reported rarely.

Respiratory, Thoracic and Mediastinal Disorders
Dyspnoea has been reported commonly.

Skin and Subcutaneous Tissue Disorders
Hyperhidrosis and pruritis have been reported commonly. There have been uncommon reports of rash, photosensitivity reaction and dermatitis.

Toxic and Allergic
Isolated cases of hyperbilirubinaemia, jaundice, SLE and haemolytic-uraemic syndrome have been reported. Blood dyscrasias (leukopenia, neutropenia, agranulocytosis, pancytopenia, aplastic anaemia, thrombocytopenia and thrombocythaemia) have been reported with flupentixol but the causality has not been confirmed.

Increased levels of AST, ALT and alkaline phosphatase have also been reported. Other antipsychotic drugs have been associated with leukopenia, agranulocytosis, thrombocytopenic or nonthrombocytopenic purpura, haemolytic anaemia and pancytopenia.

Skin reactions, such as rash, and erythema have rarely been reported with flupentixol (frequency < 1 %). Alopecia and eczema have also been reported with flupentixol. The possibility of hypersensitivity and anaphylactoid reactions occurring in some patients should be borne in mind.

Vascular Disorders
Hypotension and hot flush have been reported uncommonly and cases of venous thromboembolism very rarely.

Discontinuation
Abrupt discontinuation of flupentixol decanoate may be accompanied by withdrawal symptoms. The most common symptoms are nausea, vomiting, anorexia, diarrhoea, rhinorrhoea, sweating, myalgias, paraesthesias, insomnia,

Genotoxicity
No data available.

Carcinogenicity
No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Fractionated coconut oil

6.2 Incompatibilities
Flupentixol decanoate should not be mixed with depot formulations that use sesame oil as the vehicle, because this would result in definite changes in the pharmacokinetic properties of the involved preparations.

6.3 Shelf life
In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 Special precautions for storage
Store below 25°C. Protect from light.

6.5 Nature and contents of container
Fluanxol Depot
- Solution for injection containing 20 mg/mL flupentixol decanoate.
- 1 mL (20 mg) and 2 mL (40 mg) glass ampoules in packs of 5 ampoules.

Fluanxol Concentrated Depot
- Concentrated injection containing 100 mg/mL flupentixol decanoate.
- 1 mL (100 mg) glass ampoules in packs of 5 ampoules.

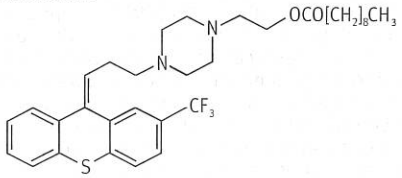
6.6 Special precautions for disposal
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 Physicochemical properties
Chemical name:
cis (z)-2-[4-[3-(2-(trifluoromethyl) thioxanthenylidene - (9)) propyl] - piperaziny - (1)] ethanol - (1) decanoic acid ester

Molecular formula:
$C_{33}H_{43}F_3N_2O_2S$

Molecular weight:
588.82

Chemical structure



CAS number
30909-51-4

7 MEDICINE SCHEDULE (POISONS STANDARD)
S4 - Prescription only medicine

8 SPONSOR
Australian Sponsor:
Lundbeck Australia Pty Ltd
1 Innovation Road
North Ryde NSW 2113
Ph: 02 8669 1000

New Zealand Sponsor:
Pharmacy Retailing t/a
Healthcare Logistics
58 Richard Pearse Drive
Mangere
Auckland 2022
Ph: 0800 540 555

9 DATE OF FIRST APPROVAL
13 July 1994

10 DATE OF REVISION
23 September 2020

Summary table of changes

Section Changed	Summary of new information
8	NZ sponsor address