SUMMARY OF PRODUCT CHARACTERISTICS

Fluphegood 25 mg/ml Solution for Injection (Fluphenazine Decanoate)

1. NAME OF THE MEDICINAL PRODUCT

Fluphegood 25 mg/ml Solution for Injection (Fluphenazine Decanoate BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 25 mg fluphenazine decanoate (250 mg per 10 ml vial).

Excipients with known effect:

Each ml contains 15 mg benzyl alcohol (E1519) and sesame oil. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

A clear yellow, oily solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In the long-term management of psychotic disorders such as chronic schizophrenia, the disturbed elderly, severe anxiety tension states and personality disorders.

Fluphegood is not intended for use in non-psychotic disorders or for short-term therapy (less than 3 months). Fluphegood has not been shown to be effective in the management of behavioural complications in patients with mental retardation.

4.2 Posology and method of administration

Adults

The usual initial dose is 12.5 mg. Subsequent dosage is usually 25 mg every 2 to 4 weeks, with a range of 12.5 to 100 mg depending on the patient's response. In those with no previous therapy, treatment may be initiated by the oral route or using a quick-acting agent before transferring to the depot formulation. Dosage should not exceed 100 mg. If doses greater than 50 mg are deemed necessary, the next dose and succeeding doses should be increased cautiously in increments of 12.5 mg.

Severely agitated patients may be treated initially with a rapid-acting phenothiazine such as fluphenazine hydrochloride injection. When acute symptoms have subsided, 25 mg (1 ml) of Fluphegood may be administered; subsequent dosage is adjusted as necessary.

Elderly

Elderly patients may be particularly susceptible to extrapyramidal reactions. The usual initial dose should be 6.25 mg. Reduced maintenance dosage may be required.

Children

Not recommended for children.

Note

The dosage should not be increased without close supervision. There is variability in individual response. The response to antipsychotic drug treatment may be delayed. If drugs are withdrawn, recurrence of symptoms may not become apparent for several weeks or months.

Method of administration

Deep intramuscular injection. Fluphegood is for intramuscular injection only. Do not administer intravenously. Patients taking this medication should carry a treatment card indicating dosage received.

4.3 Contraindications

- Comatose states.
- Suspected or established subcortical brain damage.

- Marked cerebral atherosclerosis.
- Phaeochromocytoma.
- Renal failure.
- Liver failure.
- Severe cardiac insufficiency.
- Severely depressed states.
- Hypersensitivity to fluphenazine decanoate, any other phenothiazine, or to any of the excipients listed in section 6.1.
- Patients receiving large doses of CNS depressants (e.g. alcohol, barbiturates, narcotics, hypnotics).
- Existing blood dyscrasias.

4.4 Special warnings and precautions for use

General precautions

Caution should be exercised in patients with the following conditions: liver disease; cardiac arrhythmias, mitral insufficiency, risk factors for stroke, cardiovascular disease or family history of QT prolongation; thyrotoxicosis; severe respiratory disease; Parkinson's disease; patients who have developed cholestatic jaundice, dermatoses or other allergic reactions to phenothiazine derivatives; personal or family history of narrow-angle glaucoma; hypothyroidism; myasthenia gravis; prostatic hypertrophy. Cross-sensitivity may occur in patients with a history of sensitivity to other phenothiazines.

Extreme temperatures and drug interactions

Exercise special caution in very hot weather, in patients exposed to extreme heat or phosphorus insecticides, and in patients with a history of convulsive disorders, as grand mal convulsions have been known to occur during therapy with fluphenazine.

Haematological monitoring

During the first months of treatment, routine blood counts and liver function tests are advisable, as blood dyscrasias (including leukopenia, agranulocytosis, thrombocytopenic or non-thrombocytopenic purpura, eosinophilia and pancytopenia) and liver dysfunction may occur. If soreness of the mouth, gums or throat, or symptoms of upper respiratory infection occur and confirmatory leukocyte count indicates bone marrow depression, therapy should be discontinued immediately.

Surgical patients

Patients undergoing surgery should be carefully monitored for possible hypotensive phenomena, and the doses of anaesthetics or other CNS depressants used may need to be reduced.

Benzyl alcohol content

This product contains 15 mg of benzyl alcohol per ml. Benzyl alcohol must not be given to premature babies or neonates. It may cause toxic reactions and anaphylactoid reactions in infants and children up to three years old.

Sesame oil content

This product contains sesame oil, which may rarely cause severe allergic reactions. Potentiation of the effects of alcohol may occur with the use of this drug.

Venous thromboembolism

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. All possible risk factors for VTE should be identified before and during treatment with Fluphegood and preventive measures undertaken.

Pneumonia

As with any phenothiazine, the physician should be alert to the possible development of pneumonia in patients under prolonged treatment.

Increased mortality in elderly patients with dementia

Data from two large observational studies showed that elderly people with dementia treated with antipsychotics are at a small increased risk of death compared with those who are not treated. Fluphegood is not licensed for the treatment of dementia-related behavioural disturbances.

Abrupt withdrawal

In general, phenothiazines do not produce psychic dependence; however, gastritis, nausea, vomiting, dizziness and tremulousness have been reported within 2 to 4 days following abrupt cessation of high-dose therapy. These symptoms can be reduced by gradual reduction of the dosage or by continuing concomitant anti-Parkinson agents for several weeks after the phenothiazine is withdrawn.

Tardive dyskinesia

Neuroleptics should be prescribed in a manner that minimises the occurrence of tardive dyskinesia. Chronic neuroleptic treatment should generally be reserved for patients with a chronic illness that is known to respond to neuroleptic drugs and for whom alternative, equally effective but potentially less harmful treatments are not available or appropriate. The smallest dose and shortest duration producing a satisfactory clinical response should be used. The need for continued treatment should be reassessed periodically.

4.5 Interaction with other medicinal products and other forms of interaction

Antihypertensives:

The antihypertensive action of guanethidine, clonidine and possibly other adrenergic-blocking antihypertensive agents may be blocked. Clonidine may decrease the antipsychotic activity of phenothiazines.

Drugs that prolong the QT interval:

Drugs that can prolong the QT interval should be avoided, as should any drug that can cause electrolyte imbalance or increase the concentration of fluphenazine in the blood.

CYP450 2D6 substrates or inhibitors:

Fluphenazine is metabolised by CYP2D6 and is itself an inhibitor of this enzyme. The plasma concentrations and effects of fluphenazine may therefore be increased and prolonged by drugs that are substrates or inhibitors of CYP2D6, possibly resulting in cardiac toxicity, anticholinergic side effects or orthostatic hypotension. Examples include anti-arrhythmics, certain antidepressants (SSRIs, tricyclics), certain antipsychotics, beta-blockers, protease inhibitors, opiates and cimetidine.

CNS depressants/Alcohol/Analgesics:

The patient's response to alcohol and other CNS depressants (hypnotics, sedatives, strong analgesics) may be exaggerated while taking Fluphegood. Combined use with narcotic analgesics may cause hypotension as well as CNS or respiratory depression.

Tricyclic antidepressants:

Phenothiazines impair the metabolism of tricyclic antidepressants. Serum concentrations of both the tricyclic and phenothiazine are increased. Sedative and antimuscarinic effects may be potentiated. Tricyclics may increase the potential for arrhythmia.

Lithium:

Neurotoxicity has been reported when lithium is used concomitantly with fluphenazine.

ACE inhibitors/Thiazide diuretics:

Hypotension may result via additive or synergistic pharmacological activity.

Beta-blockers:

Plasma levels of both drugs may be increased. Dosage reduction of both drugs is recommended.

Metrizamide:

Phenothiazines may predispose patients to metrizamide-induced seizures. Discontinue fluphenazine for 48 hours prior to and for at least 24 hours after myelography.

Epinephrine and other sympathomimetics:

Phenothiazines may antagonise the action of adrenaline and other sympathomimetics and may cause severe hypotension. If hypotension should occur, use levarterenol bitartrate; epinephrine should NOT be used as its action may be reversed by phenothiazine derivatives, resulting in a further lowering of blood pressure.

Levodopa:

Phenothiazines may impair the anti-Parkinson effect of levodopa.

Anticholinergics/Antimuscarinics:

Cholinergic blockade may be exaggerated, especially in older patients. Close supervision and careful dosage adjustment are required.

Anticonvulsants:

Anticonvulsant action may be impaired by Fluphegood.

Monoamine oxidase inhibitors:

Fluphegood may increase the effect of MAO inhibitors.

Quinidine and other antiarrhythmics:

The cardiac-depressant effects may be enhanced by phenothiazines.

4.6 Fertility, pregnancy and lactation

Pregnancy

Phenothiazines should only be used during pregnancy if considered essential by the physician. Neonates exposed to antipsychotics including Fluphegood during the third trimester 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. Newborns should be monitored carefully. The lowest possible dose should be administered for the shortest duration.

Breast-feeding

Since fluphenazine is excreted in breast milk, Fluphegood should not be used during lactation in women who are breast-feeding.

Fertility

Hormonal effects of fluphenazine include hyperprolactinaemia, which may cause galactorrhoea, gynaecomastia, oligo- or amenorrhoea, and impairment of sexual function.

4.7 Effects on ability to drive and use machines

Phenothiazines may induce drowsiness. Persons taking Fluphegood should not drive or operate machinery unless the drug has been shown not to interfere with physical or mental ability.

4.8 Undesirable effects

Summary of the safety profile

The adverse events reported most frequently with phenothiazine compounds are extrapyramidal symptoms including pseudoparkinsonism, dystonia, dyskinesia, akathisia, oculogyric crises, opisthotonos and hyperreflexia. Most are reversible but may be persistent. Neuroleptic Malignant Syndrome (NMS) is a potentially fatal syndrome that may occur with any neuroleptic agent.

Tabulated list of adverse reactions

Frequencies: all adverse reactions below are categorised as "Not known" (frequency cannot be estimated from the available data), as per the submitted SmPC.

System Organ Class (MedDRA)	Preferred Term	Frequency
Blood and lymphatic system disorders	Pancytopenia, agranulocytosis, thrombocytopenic purpura, non-thrombocytopenic purpura, leukopenia, eosinophilia	Not known
Immune system disorders	Anaphylactic reaction	Not known
Metabolism and nutrition disorders	Inappropriate antidiuretic hormone secretion, hyponatraemia, anorexia, weight fluctuation	Not known
Psychiatric disorders	Restlessness, agitation, abnormal dreams	Not known
Nervous system disorders	Neuroleptic malignant syndrome, cerebrovascular accident, brain oedema, tardive dyskinesia, extrapyramidal disorder, parkinsonism, dystonia, dyskinesia, akathisia, oculogyration, opisthotonos, hyperreflexia, choreoathetosis, somnolence, lethargy, EEG abnormal, headache	Not known
Eye disorders	Glaucoma, vision blurred, lenticular opacities, corneal opacity	Not known
Cardiac disorders	Cardiac arrest, torsades de pointes, ventricular arrhythmia, ventricular fibrillation, ventricular tachycardia, QT interval prolongation, ECG abnormal	Not known
Vascular disorders	Hypertension, blood pressure fluctuation, hypotension, thromboembolic disorders (including pulmonary embolism and deep vein thrombosis)	Not known
Respiratory disorders	Asthma, laryngeal oedema, nasal congestion	Not known

System Organ Class (MedDRA)	Preferred Term	Frequency
Gastrointestinal disorders	Paralytic ileus, faecaloma, dry mouth, constipation, salivary hypersecretion, nausea, vomiting	Not known
Hepatobiliary disorders	Hepatitis, cholestatic jaundice, jaundice, liver function test abnormal	Not known
Skin and subcutaneous tissue disorders	Exfoliative dermatitis, angioneurotic oedema, photosensitivity reaction, urticaria, seborrhoea, erythema, eczema, hyperhidrosis, pruritus, pigmentation disorder, systemic lupus erythematosus	Not known
Renal and urinary disorders	Acute renal failure, neurogenic bladder, polyuria	Not known
Reproductive system and breast disorders	Gynaecomastia, irregular menstruation, lactation disorder, erectile dysfunction, libido disorder	Not known
General disorders and admin. site conditions	Sudden death, peripheral oedema, pyrexia	Not known
Investigations	Pregnancy test false positive, blood creatine phosphokinase increased	Not known
Pregnancy/perinatal conditions	Drug withdrawal syndrome neonatal	Not known

Description of selected adverse reactions

Neuroleptic Malignant Syndrome (NMS): A potentially fatal syndrome characterised by clouding of consciousness, rigidity and other extrapyramidal effects, and autonomic dysfunction (irregular pulse or blood pressure, tachycardia, diaphoresis, cardiac dysrhythmias) — most importantly hyperpyrexia. Leukocytosis, elevated CPK, liver function abnormalities and acute renal failure may also occur. Treatment involves immediate cessation of neuroleptic therapy and intensive symptomatic management. If antipsychotic treatment is required after recovery from NMS, the patient should be carefully monitored as recurrences have been reported.

Tardive dyskinesia: A syndrome of involuntary dyskinetic movements that may develop in patients on chronic antipsychotic therapy. Those at particular risk include the elderly, females and patients on high-dose or prolonged therapy. Fine, vermicular movements of the tongue may be an early sign. The syndrome may be irreversible.

Hypotension: Patients with phaeochromocytoma, cerebrovascular or renal insufficiency, or severe cardiac reserve deficiency appear particularly prone to hypotensive reactions. Levarterenol bitartrate is the most suitable vasopressor; epinephrine must NOT be used.

Cardiac effects: ECG changes with QT prolongation and T-wave changes have been reported commonly at moderate to high dosage. These are reversible on dose reduction. In rare cases, serious arrhythmias have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

The symptoms of overdose are extensions of known pharmacological effects and adverse reactions, the most prominent of which would be: (1) severe extrapyramidal reactions, (2) hypotension, or (3) sedation. CNS depression may progress to coma with areflexia. Restlessness, confusion and excitement may occur with early or mild intoxication.

Management: Withdraw the drug. If severe hypotension should occur, use intravenous vasopressors — levarterenol bitartrate is the drug of choice; epinephrine should NOT be used. For severe extrapyramidal reactions, administer anti-Parkinson medication and continue for several weeks, then withdraw gradually to avoid rebound extrapyramidal symptoms. Phenothiazines are not dialyzable; haemodialysis, peritoneal dialysis, exchange transfusions and forced diuresis are ineffective.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antipsychotics; phenothiazines with piperazine structure. ATC code: N05AB02.

Fluphenazine decanoate is an ester of the potent neuroleptic fluphenazine, a phenothiazine derivative of the piperazine type. The ester is slowly absorbed from the intramuscular injection site and is then hydrolysed in the plasma to the active therapeutic agent, fluphenazine. Fluphenazine exerts its antipsychotic effects primarily through blockade of dopamine D2 receptors. Extrapyramidal reactions are not uncommon with fluphenazine; however, it does not have marked sedative or hypotensive properties compared to other phenothiazines.

5.2 Pharmacokinetic properties

Fluphenazine decanoate is a long-acting depot preparation. Following deep intramuscular injection, the drug is slowly released from the oil vehicle and hydrolysed to free fluphenazine. Fluphenazine is a phenothiazine derivative that is widely distributed, metabolised in the liver and excreted via the kidney and enterobiliary tract. The apparent half-life is 2.5 to 16 weeks, reflecting slow release from the depot injection site. Plasma concentrations are sustained, allowing dosing intervals of 2 to 4 weeks.

5.3 Preclinical safety data

No further preclinical safety information is available beyond the clinical experience reflected in other sections of this SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the solution for injection:

Benzyl alcohol (E1519) — excipient with known effect

Sesame oil — excipient with known effect

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 1 year.

Once opened: Use within 28 days of first opening. Discard any unused portion.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Keep vial in the outer carton to protect from light.

6.5 Nature and contents of container

Type I amber glass vial (10 ml) with white rubber stopper and aluminium seal. Each vial is packed in a cardboard carton with a package leaflet.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER

GOODMED HEALTHCARE LTD

P.O. Box 76337-00508, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD12162/26268

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

10.10.2025

10. DATE OF REVISION OF THE TEXT

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