NHS Greater Glasgow & Clyde
Mental Health Services

Protocol for the use of Unlicensed Fluphenazine Decanoate Injection

Indication

Sanofi the manufacturer of Modecate injection (Fluphenazine decanoate) ceased production of the preparation in 2018 and all licensed stock will cease to be available by August 2020. An unlicensed version can be imported from Germany to enable treatment to be maintained for those legacy patients unable to switch to a licensed alternative long acting injection.

Fluphenazine decanoate was licensed for the treatment and maintenance of patients with schizophrenia and paranoid psychoses[5].

Informed consent

Due to its unlicensed status, explanation for the rationale of treatment choice should be given at a suitable time during the patient's treatment. Patient information explaining unlicensed medication in general terms is available via the Choice and Medication portal[2], as is a specific fluphenazine decanoate leaflet.

Documentation

The consultant psychiatrist must make a clear record of the rationale for prescribing an unlicensed medication within the patient's case notes and document the discussion with the patient[1]. Nursing staff in the ward must be informed of the medicine's unlicensed status and ward clinical pharmacists must ensure that staff are aware of the unlicensed status.

When ordering fluphenazine decanoate injection, the patient's initials and CHI should be included on the requisition as well as the phrase "as per protocol" for the order to be processed.

A record of administration of unlicensed medication must be kept (as per unlicensed medication policy[3]). When entering administration on HEPMA, the drug batch number and expiry date should be recorded when prompted. It is the responsibility of the nurse in charge to ensure this occurs.

When supplying fluphenazine decanoate injection from pharmacy, pharmacy staff must ensure that batch numbers are documented on the requisition.

Review & Monitoring

Patients must be reviewed and monitored in accordance with NHS GG&C Policy, MHS 30-Good Practice Statement for the use of Depot and Long Acting Antipsychotic Injections[4].

Dose range[5]

- **Adults:** a test dose of 12.5mg should be administered by deep intramuscular injection into the gluteal region. The onset of action generally appears between 24 and 72 hours after injection and the effects of the drug on psychotic symptoms become significant within 48 to 96 hours. Subsequent injections and the dosage interval are determined in accordance with the patient's response. When administered as maintenance therapy, a single injection may be effective in controlling schizophrenic symptoms for up to four weeks or longer.

  It is desirable to be as flexible in the dose as possible to achieve the best therapeutic response with the least side effects. Most patients are successfully maintained within the dose range **12.5 – 100mg** given at an interval of **2 to 5 weeks.**

  Patients suffering a relapse following cessation of fluphenazine decanoate may be restarted on their previous dose although the frequency of injections may need to be increased in the early weeks of treatment until satisfactory control is obtained.

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- **Elderly:** elderly patients may be particularly susceptible to extra-pyramidal reactions. Consequently a reduced initial dose (6.25mg) and a lower maintenance dose may be required.

Side effects[2,5]

Very common (>1 in 10)

- Sleepiness
- Extra-pyramidal movement disorders
- Constipation
- Dry mouth
- Blurred vision
- Weight gain
- Pain at the injection site

Common (> 1 in 100)

- Hyperprolactinaemia
- Postural hypotension
- Sexual dysfunction

Rare (> 1 in 1000)

- Urinary retention
- Venous thrombomembolism
- Neuroleptic Malignant Syndrome (NMS)
- Tardive Dykinesia
- QTc prolongation

Contraindications[5]

- Hypersensitivity to fluphenazine decanoate or any other excipients in the injection.
- Comatose states
- Marked cerebral atherosclerosis
- Phaeochromocytoma
- Renal failure
- Liver failure
- Severe cardiac insufficiency
- Severely depressed states
- Existing blood dyscrasias

Cautions[5]

- Liver disease
- Renal impairment
- Cardiac arrhythmias, cardiac disease
- Thyrotoxicosis
- Severe respiratory depression
- Epilepsy and conditions predisposing to epilepsy (e.g. alcohol withdrawal or brain damage)
- Parkinson's disease
- Patients with known sensitivity to phenothiazines
- Personal or family history of narrow angle glaucoma
- Hypothyroidism
- Myasthenia gravis
- Prostatic hypertrophy

Interactions[5]

- Other drugs that produce CNS depression e.g. alcohol, general anaesthetics, hypnotics, sedatives or strong analgesics
- Antagonise the action adrenaline and other sympathomimetic agents
- Impair the effect of levodopa
- Impair the effect of anti-convulsants
- Increase the effect of anticoagulants and antidepressants
- Lithium
- Other drugs known to prolong QTc
- MAOIs

References

1. GMC Good practice in prescribing and managing medicines and devices. Updated Apr 21

2. Choice and Medication. Unlicensed medications handy fact sheet and fluphenazine PIL

3. NHS Greater Glasgow and Clyde Area Drug and Therapeutics Committee Policies Relating to the Management of Medicines Section 9.1

4. NHS GG&C MHS 30 Good Practice Statement for the use of Depot and Long Acting Antipsychotic Injections

5. Electronic Medicines Compendium Modecate SPC 2015