

Flupenthixol decanoate

Product: FLUPENTHIXOL DECANOATE (Fluanxol Depot®) 20mg/mL and 100mg/mL

Class of drugs:
Long-acting antipsychotic agent

Indication:
Treatment of schizophrenia

Manufacturer: Lundbeck Canada Inc.

CED Recommendation

The CED recommended that flupenthixol decanoate (Fluanxol Depot®) 20mg/mL and 100mg/mL ampoules be listed on the Ontario Drug Benefit Formulary as a General Benefit, replacing the vials that are being discontinued by the manufacturer.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to list flupenthixol decanoate (Fluanxol Depot®) on the Ontario Drug Benefit Formulary as a General Benefit.

Status

Funding available through Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Flupenthixol decanoate 20mg/mL 1mL ampoules and 100mg/mL 1mL ampoules are new packaging formats for an existing line of products.
- ◆ Flupenthixol decanoate 200mg/2mL vials and 200mg/10mL vials are already listed on the ODB Formulary but are being discontinued by the manufacturer.
- ◆ The manufacturer introduced the new form of the drug, in ampoules, to suit the needs and volume of doses administered to patients.
- ◆ There are no changes in the formulation of the product and no major concerns with the stability of the product packaged as ampoules.
- ◆ **Overall, the Committee noted that the ampoules will be cost-neutral to the program and recommended replacing the vials.**

Background:

Schizophrenia is a complex mental illness. A biochemical imbalance in the brain may cause the symptoms of schizophrenia, which can include hallucinations, delusions, disorganized thinking, impaired judgment, impulsiveness, social withdrawal, and difficulties with perception, memory, or abstract thinking.

There is no cure for schizophrenia, antipsychotic medications can help control the symptoms of the illness by changing the balance of chemicals in the brain. Medications are only a part of a comprehensive treatment plan that includes education, counseling and social support programs.

Flupenthixol decanoate is a long-acting injection in the class of drugs called antipsychotics. The medication is dissolved in sesame or coconut oil and is slowly released into the body over a few weeks, following an injection. This drug is used to treat patients with non-agitated chronic schizophrenia.

Detailed Discussion:

- ◆ Flupenthixol decanoate will now be available in 1mL ampoules instead of a multi-vial dosage format. This is a new packaging format for the same product already listed on the Formulary, for the treatment of non-agitated chronic schizophrenia.
- ◆ The Committee had no major concerns about stability or degradation to light exposure.
- ◆ There is no change in the cost per mL of the product.
- ◆ **Overall, the Committee recommended that flupenthixol decanoate ampoules be listed as General Benefit on the ODB Formulary, similar to the existing flupenthixol decanoate vials.**

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review flupenthixol decanoate (Fluanxol Depot®) 20mg/mL and 100mg/mL ampoules.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care
Ontario Public Drug Programs
Hepburn Block, 9th Floor
80 Grosvenor Street, Queen's Park
Toronto, Ontario M7A 1R3
or click: http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html